

EPAUnited States Environmental Protection Agency
Washington, DC 20460**Work Assignment**

Work Assignment Number

B-01

☐ Other ☐ Amendment Number:

Contract Number

EP-C-11-005

Contract Period 01/01/2011 To 12/31/2011

Base ☒

Option Period Number

Title of Work Assignment/SF Site Name

RWQC

Contractor

ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

3.1, 3.4, 3.5, 3.6

Purpose:

☐

Work Assignment

☐

Work Assignment Close-Out

☐

Work Assignment Amendment

☐

Incremental Funding

☒

Work Plan Approval

Period of Performance

From 01/01/2011 To 12/31/2011

Comments:

The cumulative total of \$642,474 includes the original work plan and the amendment work plan 1 costs and level of effort hours.

☐

Superfund

Accounting and Appropriations Data

☒

Non-Superfund

SFO
(Max 2)☐

Note: To report additional accounting and appropriations data use EPA Form 1900-68A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:

01/01/2011 To 12/31/2011

Cost/Fee:

LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: 07/26/2011

Cost/Fee: \$407,921.00

LOE: 3,220

Cumulative Approved:

Cost/Fee: \$642,474.00

LOE: 5,220

Work Assignment Manager Name Sharon Nappier

Branch/Mail Code:

Phone Number 202-566-0740

FAX Number:

(Signature)

(Date)

Project Officer Name Shirley Harrison

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

(Signature)

(Date)

Other Agency Official Name

Branch/Mail Code:

Phone Number:

FAX Number:

(Signature)

(Date)

Contracting Official Name Donna Reinhart

Branch/Mail Code:

Phone Number: 513-487-2114

FAX Number:

(Signature)

(Date)

B-01

PERFORMANCE WORK STATEMENT

TECHNICAL AND REGULATORY SUPPORT FOR THE DEVELOPMENT OF CRITERIA FOR WATER MEDIA (MICROBIOLOGY EMPHASIS)

1.0 INTRODUCTION

1.1 Background

The mission of the United States Environmental Protection Agency's Office of Water (OW) under the Safe Drinking Water Act and the Clean Water Act includes protecting the public health from the adverse effects of microbial pollutants (e.g., chemicals and microorganisms) in media such as surface water, drinking water, wastewater, sewage sludge, and sediments. In fulfillment of this mission, OW's Office of Science and Technology (OST) develops effluent guidelines, human health criteria, implementation guidance for health advisories, maximum contaminate level goals, and limits for pollutants in various water media.

1.2 Purpose of Contract

The purpose of this contract is to provide technical and regulatory support services to the Health and Ecological Criteria Division (HECD) in OST for the development of human health criteria, implementation guidance for health advisories, maximum contaminate level goals, and pollutant limits concerning the adverse effects of microbial pollutants in media such as surface water, drinking water, wastewater, sewage sludge and sediments. This support includes direct activities and related activities such as conducting literature reviews, conducting risk assessments, performing statistical analyses, evaluating pollutants selected for review by the United States Environmental Protection Agency (EPA), assessing the potential impact of criteria on sensitive populations, preparing criteria documents, preparing health advisories, preparing technical guidance documents, preparing technical support documents for regulatory requirements, preparing the index of references for proposed and final regulations, summarizing comments on proposed regulations, and arranging and conducting workshops.

2.0 GENERAL TASKS

2.1 The contractor shall furnish all facilities, materials, equipment, and necessary professional, technical, and support personnel in support of the effort delineated below. The initial submission of all documents shall be in draft form for EPA review and comment. Required revisions will be provided to the contractor by EPA for incorporation into a final document.

2.2 The contractor shall possess or have access to appropriate equipment/software to perform mathematical modeling and statistical analyses in support of criteria development.

2.3 The contractor shall develop documents and data bases using EPA standard software (e.g., Word, Excel, and Lotus Notes), as specified in a work assignment. Software documentation shall be accessible to the EPA Work Assignment Manager (WAM) and other persons authorized by the EPA Project Officer (PO).

2.4 The contractor shall possess or have access to a laboratory that can analyze microbial pollutants (e.g., standard analytical methods for pathogens including molecular methods) in water media (e.g., wastewater, ground and or surface water, drinking water, sediment and sewage sludge), hereinafter referred to as water media, as specified in a work assignment. The contractor shall prepare a Quality Assurance Project Plan (QAPP) for work assignments that require environmental measurements or the use of secondary data.

2.5 The contractor shall provide information that will be used by EPA for quick responses and analyses of options, issues, and policy decisions as they relate to the tasks in this Performance Work Statement (PWS). Quick responses are those

that require completion in one to seven days, or as specified in a work assignment. EPA will review the results of all contractor analyses, and make a final determination with regard to program objectives and policy decisions.

2.6 The contractor shall comply with the requirements for studies and rulemaking records contained in authorities such as the Administrative Procedures Act, the Paperwork Reduction Act, the Clean Water Act, OMB Circular A-130 for management of Federal Information Resources, and the Federal Rules of Appellate Procedure (Rules 16 and 17, 28 U.S.C. Appendix).

2.7 The contractor shall perform the specific tasks in the PWS in accordance with the appropriate EPA risk assessment guidance and science policy guidance (e.g., guidance on the development of a human health criteria document), as indicated in a work assignment.

3.0 SPECIFIC TASKS

3.1 Preparation of Human Health Documents

3.1.1 The contractor shall prepare summaries of peer-reviewed literature on infectivity, and clinical and epidemiological endpoints, as specified in a work assignment. Each summary shall discuss the test protocol (e.g., endpoints measured; test species; the number, sex, and species of the control group and dosing group; the method, frequency, and duration of dosing), and shall evaluate the test protocol. Similarly, for epidemiological studies, the contractor shall evaluate the protocol, type of study (e.g., case-controlled, community, prospective, or retro prospective), analyses, and conclusions according to criteria as specified as appropriate by the WAM or CO.

3.1.2 The contractor shall prepare screening analyses that display and compare all available data for a microbial pollutant, and build on the summaries in subsection 3.1.1. If required by the work assignment, these analyses shall be presented as electronic data bases.

The contractor shall be able to develop figures, tables or other graphics to display the array of available data for a microbial pollutant building on the summaries in subsection 3.1.1. The requested data arrays may be used to assist in risk communication, facilitate the dose-response assessment and/or improve the transparency of health effects support documents.

The contractor shall collect data, prepare screening analyses and participate in the development of screening methodologies for microbial contaminants that will be useful in the development of future Critical Contaminant Lists (CCLs), prioritizing resources, and in identifying emerging contaminants.

3.1.3 The contractor shall be familiar with Federal and private exposure data bases and obtain them as needed for use in developing assessments. The contractor shall document the methodology, assumptions, and rationales used in the analyses. EPA will make the final decision concerning any recommended finding based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.4 The contractor shall prepare, evaluate, and revise exposure and health effects documents. These documents provide information on the criteria that protect human health from exposure to a microorganism in water media. The contractor shall document the methodology, assumptions, and rationales used for this task. EPA will make the final decision concerning any recommended health effects document based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor

provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion

A health effects document for a microorganism shall address, as specified in a work assignment: (1) physical and biological properties of the microorganism; (2) occurrence and environmental fate and transport; (3) infectivity; (4) human exposure to the microorganism; (5) health effects for animals; (6) health effects for humans; (7) mechanisms of infectivity; (8) magnitude of infectious disease effects; (9) a summary of the results of health effects documents prepared by other Federal agencies; and (10) any other areas set forth in the work assignment.

During the development of a health effects document, the contractor shall conduct literature reviews to augment the file of references provided by the EPA PO/WAM with other references.

3.1.5 The contractor shall prepare, evaluate, and revise health advisories for microorganisms. A health advisory provides information that public health officials use to help determine control priorities for pollutants in water as well as providing general information for the public. The contractor shall document the methodology, assumptions, and rationale used to prepare, evaluate, and revise a health advisory. EPA will make the final decision concerning any recommended health advisory based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

A health advisory for a microorganism shall address: (1) general information and properties of the microorganism; (2) occurrence and environmental fate and transport; (3) infectivity; (4) health effects in animals and humans; (5) treatability; (6) magnitude of infectious disease effects; and (7) any other areas set forth in the work assignment.

During the development of a health advisory, the contractor shall conduct literature reviews to augment the file of references provided by the EPA PO/WAM with other references.

3.1.6 The contractor shall provide technical support for the preparation, evaluation, and revision of hazard, exposure, or risk assessment/characterization techniques or methodologies for human health protection. This includes, among other things, providing technical support during the development of methodologies used to develop human health criteria for various water media. The contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning any recommended technique or methodology based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.7 The contractor shall provide on a rapid response basis (as defined in 2.6) analyses of human health risk assessment guidelines for microorganisms, results of human health risk assessments, and treatment technology practices and procedures. This includes, among other things, analysis of the impact of criteria on sensitive populations, and analyses of dose response and infectivity data and exposure data.

3.1.8 The contractor shall prepare, evaluate, and revise technical guidance documents and position papers for microorganisms. These documents provide information on the principles for criteria development (e.g., minimum data requirements and exposure assumptions). The contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning any recommended technical guidance document based on

its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.9 The contractor shall evaluate "raw" data generated from an infectivity or epidemiology study. The raw data will be provided by the EPA PO/WAM. The evaluation shall include a complete description of the protocol used to gather the data; analyses of effects observed, including tabulation of all observations; evaluation of biological significance of endpoints according to EPA published guidelines or other technical documents; statistical analyses of the significance of observations; and conclusions as to existence of exposure-related effects and their implications for human health.

3.1.10 The contractor shall conduct appropriate statistical analyses of infectivity data, or epidemiological data, or exposure data, as specified in a work assignment. These analyses shall be completed in accordance with EPA published guidance or other technical documents.

3.1.11 The contractor shall provide analyses of food and water consumption patterns and associated exposure to infectious agents through foods for the U.S. population. These analyses shall include frequency and amount of specific foods consumed by sex, age, and geographical locations. Data to be analyzed shall include data from Federal data collection efforts, State collection efforts, and special studies. Similarly, the contractor shall provide analyses of exposure data from the Center for Disease Control National Health and Nutrition Examination Survey data base and the EPA National Human Exposure Assessment Survey data base, water quality data from U.S. Geological Survey and morbidity and mortality data on food and waterborne illnesses from available databases and other sources as deemed appropriate.

3.1.12 All of the above tasks and deliverables shall be completed in accordance with EPA published guidelines where available.

3.2 Sewage Sludge

3.2.1 The contractor shall provide technical support during the preparation, evaluation, and revision of procedures for selecting microbial pollutants-of-concern in sewage sludge that is used or disposed of, and shall provide technical support during the evaluation of those pollutants. The contractor shall document the methodology, assumptions, and rationale used for conducting this task. EPA will make the final decision concerning any recommended procedures to be used to select pollutants-of-concern and the evaluation of those pollutants based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.2.2 The contractor shall conduct exposure pathway risk assessments for microbial pollutants in sewage sludge applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator. The pathways evaluated for each use or disposal practice shall be the pathways evaluated for each use or disposal practice when the Standards for the Use or Disposal of Sewage Sludge (40 CFR Part 503) were developed, as well as other pathways specified in a work assignment. Results of these risk assessments will be used by EPA to develop limits for pollutants in sewage sludge.

3.2.3 The contractor shall provide technical support during the development of the rationales for the technology-based requirements in a sewage sludge use or disposal standard for pathogens and vector attraction reduction. The contractor shall document the methodology, assumptions, and rationales for this task (e.g.,

the rationale for the 38 percent volatile solids reduction requirement for vector attraction reduction). EPA will make the final decision concerning any recommended operational standard for pathogens and vector attraction reduction based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.2.4 The contractor shall prepare, evaluate, and revise technical support documents for a standard for the use or disposal of sewage sludge. These documents contain the rationales for the requirements (i.e., general requirements; pollutant limits; management practices; operational standards; and frequency of monitoring, record keeping, and reporting requirements) in a sewage sludge use or disposal standard (see 40 CFR Part 503). The contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning any recommended technical support document based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.3 Statistics Support

3.3.1 The contractor shall have statistical analyses capabilities to perform analyses of environmental data for microbial pollutants to derive descriptive or interpretative statistics.

3.3.2 The contractor shall conduct laboratory/field studies to support the development of water quality criteria, sewage sludge pollutant limits, and other program requirements, as specified in a work assignment.

3.3.3 The contractor shall perform statistical analyses of data from sampling to derive descriptive or interpretive statistics.

3.4 Administrative Record Support

The contractor shall provide data and documentation to be used by EPA in the analysis of technical issues and options for proposed and final regulations, as specified in a work assignment. Deliverables under this task include data summaries, technical reports, option papers, issue papers, and public and confidential records and files. The contractor shall describe and document the data gathering activities; display, characterize, and interpret the data and information collected; obtain copies of any references used; and describe all methodologies used. Written reports and corresponding records and files shall be prepared and organized, indexed, and cross-referenced in an administrative record for a proposed or final regulation so that the analyses and conclusions can be reproduced based on the information in the administrative record for a proposed or final regulation.

3.5 Rule making support

The contractor shall prepare Federal Register notices of EPA criteria and other regulatory documents and will index and summarize public comments on proposed regulations. Using information provided by EPA (i.e., typically public comments submitted in response to a proposed regulation and information collection requests), the contractor shall prepare an index of issues in the information provided by EPA, and cross reference those issues to the public comments. For technical issues assigned by the EPA PO/WAM, the contractor shall, based on knowledge of the appropriate rule making, prepare draft technical responses to the issues in the public comments including all relevant citations to the administrative record. EPA will review the draft technical responses, and prepare the final responses to the comments.

3.6 Preparation of outreach materials

3.6.1 The contractor shall develop outreach materials in support of the tasks in this PWS. These materials include brochures, presentation boards, slide shows, fact sheets, pamphlets, posters, videos, INTERNET layouts, and models. The materials shall be developed for use in media events (e.g., press releases). In addition, the contractor shall provide materials for distribution at presentations. All materials shall be provided in accordance with the limitations set for in the Section H clause titled "PRINTING (EPAAR 1552.208-70)." The contractor shall provide a draft of all materials for approval by the EPA PO/WAM, and shall prepare the final materials based on the EPA PO's/WAM's comments on the draft materials. For print products, the contractor shall provide a camera-ready copy or digital equivalent, and a disk copy in a disk format that enables the material to be loaded onto the INTERNET. This task shall be done only in direct support of the technical requirements in this PWS.

3.6.2 The contractor shall provide, when included in a work assignment, a complete and accurate translation of foreign language articles cited in a criteria document, a health advisory, or a technical guidance document. Translations shall be performed by experienced scientific translators well-versed in statistical, biomedical, microbiological, or epidemiological terminology. The contractor shall insure that there are no terminology or language usage ambiguities that make interpretation and analysis of the findings difficult. No translations shall be made without the written approval of the Project Officer.

3.7 Arranging and conducting workshops

The contractor shall provide support in arranging workshops, conferences, training sessions, and public meetings, and obtaining appropriate individuals to address various issues. Meeting support shall be limited in scope, and shall cover only those meetings required to address the requirements in this PWS. The contractor shall arrange travel only in accordance with the authority and limitations in the Section H clause titled "APPROVAL OF CONTRACTOR TRAVEL" (i.e., the use of contract funds to reimburse travel is strictly limited to logistical support for speakers, scientists, and experts who contribute directly to the requirements of a task in this PWS). The contractor shall support EPA by: (1) providing information for meeting agendas, including typing the agendas; (2) preparing drafts of technical information for use in preparing briefing materials; (3) identifying and inviting speakers and experts to participate in a workshop; (4) arranging for meeting space when Government space is not available; (5) arranging for the appropriate audio-visual equipment; (6) providing advance announcements, registration support, visual aid preparation, logistical support, case study preparation, interactive and role-playing activity development; and (7) preparing the minutes of the meeting, including the meeting results, for approval by the EPA WAM.

EPA United States Environmental Protection Agency Washington, DC 20460									
Work Assignment Number B-01									
<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001									
Contract Number EP-C-11-005		Contract Period 01/01/2011 To 12/31/2011		Title of Work Assignment/SF Site Name Support dev of revised RWQC					
		Base X Option Period Number							
Contractor ICF INCORPORATED, L.L.C.			Specify Section and paragraph of Contract SOW 3.1, 3.4, 3.5, 3.6						
Purpose:			Period of Performance						
<input type="checkbox"/> Work Assignment			<input type="checkbox"/> Work Assignment Close-Out						
<input checked="" type="checkbox"/> Work Assignment Amendment			<input type="checkbox"/> Incremental Funding						
<input type="checkbox"/> Work Plan Approval			From 01/01/2011 To 12/31/2011						
Comments: Attached PWS is revised as noted. Additional LOE is required to accomplish the revisions in the PWS.									
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund									
SFO Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)									
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars) (Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1									
2									
3									
4									
5									
Authorized Work Assignment Ceiling									
Contract Period: 01/01/2011 To 12/31/2011		Cost/Fee:		LOE: 2,000					
This Action:				3,800					
Total:					5,800				
Work Plan / Cost Estimate Approvals									
Contractor WP Dated:		Cost/Fee:		LOE:					
Cumulative Approved:		Cost/Fee:		LOE:					
Work Assignment Manager Name Sharon Nappier							Branch/Mail Code:		
(Signature) _____							Phone Number 202-566-0740		
(Date) _____							FAX Number:		
Project Officer Name Shirley Harrison							Branch/Mail Code:		
(Signature) _____							Phone Number: 202-566-1107		
(Date) _____							FAX Number:		
Other Agency Official Name							Branch/Mail Code:		
(Signature) _____							Phone Number:		
(Date) _____							FAX Number:		
Contracting Official Name Donna Reinhart							Branch/Mail Code:		
(Signature) _____							Phone Number: 513-487-2114		
(Date) _____							FAX Number:		

**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT #B-01 Amd 1**

Title: Activities to support the development of revised Recreational Water Quality Criteria (RWQC)

Work Assignment Manager: Sharon Nappier (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Phone (202) 566-0740
E-mail: nappier.sharon@epa.gov

Alternate WAM: John Ravenscroft (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

Period of Performance: Performance Work Statement (Amd) thru December 31, 2011

Estimated LOE: 3800 hours

Purpose of Amendment: The purpose of this amendment is to add LOE hours and funding for the following Tasks below and ODCs for software to adequately cover the "response to comments" to the Recreational Water Quality Criteria Document. ODCs have also been added for travel (1-2 trips).

TASK 1 – Workplan and Monthly Progress Reports –

No changes except that the QAPP will need to be updated to add ICF's planned response to comment approach.

TASK 2 and TASK 4 –No change, remains the same

Task Area 3 - Support for developing and editing the RWQC document and other related efforts

Under Task 3.3, LOE will be allocated to address comments generated from peer-review, FAR, OMB, etc. While there are multiple ways to deal with the comments, EPA will likely choose either to use ICF's proprietary CommentWorks or an Excel add-in. The decision regarding which of the two programs that EPA will use choose for handling

comments will be provided through technical direction. Any technical direction under this amendment, the EPA WAM shall provide to the PO and CO within 5 days.

Task Area 3.3. Respond to Draft RWQC comments

The Draft RWQC will undergo several types of reviews before it is finalized. These reviews include, but are not limited to, the expert peer-review, OMB review, public comment period, and interagency review. The Contractor shall respond to all comments from all reviews and provide an updated RWQC document to the EPA WAM.

Task Area 5 - General Project Support

Additional LOE has been added for note-taking, presentations, and meeting preparation materials. Also, ODCs have been added for travel for up to 2 trips. Details on travel dates and locations will be provided by the EPA WAM through technical direction.

Task No.	DELIVERABLE	Schedule
1	1.1 Work Plan	Within 15 business days of receipt of PWS
1	1.2 Updated QAPP	Within 1 month of receipt of Amendment
2	2.0 ADP WG notes and other materials.	TBD
3	3.1 Draft RWQC	TBD
3	3.2 Supporting documents	TBD
	3.3 Draft RWQC - Response to comments	Within 1 week of the Review
3	3.4 Final RWQC	December 31 2011
4	4.1 Comprehensive list of materials for EPA docket	October 31 2011
4	4.2 Compilation of materials for EPA docket	December 31 2011
5	5.0 General Project Support	TBD

Travel: Local travel is required under this amendment. No contractor travel outside of the Washington, DC metro area is required.

Quality Assurance: same as the original PWS.

Knowledge and Skills Required: same as the original PWS.

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment		Work Assignment Number B-02								
		<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:								
Contract Number EP-C-11-005		Contract Period 01/01/2011 To 12/31/2011 Base <input checked="" type="checkbox"/> Option Period Number								
Contractor ICF INCORPORATED, L.L.C.		Title of Work Assignment/SF Site Name 2012 RWQC								
Specify Section and paragraph of Contract SOW 3.1, 3.3, 3.4, 3.6										
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 01/01/2011 To 12/31/2011								
Comments:										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund <div style="text-align: center;">Accounting and Appropriations Data</div> <input checked="" type="checkbox"/> Non-Superfund </div>										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO (Max 2) <input type="checkbox"/>										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
01/01/2011 To 12/31/2011				0						
This Action:				500						
Total:				500						
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:		Cost/Fee:		LOE:						
Cumulative Approved:		Cost/Fee:		LOE:						
Work Assignment Manager Name Sharon Nappier <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number 202-566-0740 FAX Number:				
Project Officer Name Shirley Harrison <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:				
Other Agency Official Name Shirley Harrison <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:				
Contracting Official Name Sandra Stargardt-Licis <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 513-487-2006 FAX Number:				

PERFORMANCE WORK STATEMENT

TECHNICAL AND REGULATORY SUPPORT FOR THE DEVELOPMENT OF CRITERIA FOR WATER MEDIA (MICROBIOLOGY EMPHASIS)

1.0 INTRODUCTION

1.1 Background

The mission of the United States Environmental Protection Agency's Office of Water (OW) under the Safe Drinking Water Act and the Clean Water Act includes protecting the public health from the adverse effects of microbial pollutants (e.g., chemicals and microorganisms) in media such as surface water, drinking water, wastewater, sewage sludge, and sediments. In fulfillment of this mission, OW's Office of Science and Technology (OST) develops effluent guidelines, human health criteria, implementation guidance for health advisories, maximum contaminate level goals, and limits for pollutants in various water media.

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2.3 The contractor shall develop documents and data bases using EPA standard software (e.g., Word, Excel, and Lotus Notes), as specified in a work assignment. Software documentation shall be accessible to the EPA Work Assignment Manager (WAM) and other persons authorized by the EPA Project Officer (PO).

2.4 The contractor shall possess or have access to a laboratory that can analyze microbial pollutants (e.g., standard analytical methods for pathogens including molecular methods) in water media (e.g., wastewater, ground and or surface water, drinking water, sediment and sewage sludge), hereinafter referred to as water media, as specified in a work assignment. The contractor shall prepare a Quality Assurance Project Plan (QAPP) for work assignments that require environmental measurements or the use of secondary data.

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3.0 SPECIFIC TASKS

3.1 Preparation of Human Health Documents

3.1.1 The contractor shall prepare summaries of peer-reviewed literature on infectivity, and clinical and epidemiological endpoints, as specified in a work assignment. Each summary shall discuss the test protocol (e.g., endpoints measured; test species; the number, sex, and species of the control group and dosing group; the method, frequency, and duration of dosing), and shall evaluate the test protocol. Similarly, for epidemiological studies, the contractor shall evaluate the protocol, type of study (e.g., case-controlled, community, prospective, or retro prospective), analyses, and conclusions according to criteria as specified as appropriate by the WAM or CO.

3.1.2 The contractor shall prepare screening analyses that display and compare all available data for a microbial pollutant, and build on the summaries in subsection 3.1.1. If required by the work assignment, these analyses shall be presented as electronic data bases.

The contractor shall be able to develop figures, tables or other graphics to display the array of available data for a microbial pollutant building on the summaries in subsection 3.1.1. The requested data arrays may be used to assist in risk communication, facilitate the dose-response assessment and/or improve the transparency of health effects support documents.

The contractor shall collect data, prepare screening analyses and participate in the development of screening methodologies for microbial contaminants that will be useful in the development of future Critical Contaminant Lists (CCLs), prioritizing resources, and in identifying emerging contaminants.

3.1.3 The contractor shall be familiar with Federal and private exposure data bases and obtain them as needed for use in developing assessments. The contractor shall document the methodology, assumptions, and rationales used in the analyses.

EPA will make the final decision concerning any recommended finding based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.4 The contractor shall prepare, evaluate, and revise exposure and health effects documents. These documents provide information on the criteria that protect human health from exposure to a microorganism in water media. The contractor shall document the methodology, assumptions, and rationales used for this task. EPA will make the final decision concerning any recommended health effects document based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor

provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion

A health effects document for a microorganism shall address, as specified in a work assignment: (1) physical and biological properties of the microorganism; (2) occurrence and environmental fate and transport; (3) infectivity; (4) human exposure to the microorganism; (5) health effects for animals; (6) health effects for humans; (7) mechanisms of infectivity; (8) magnitude of infectious disease effects; (9) a summary of the results of health effects documents prepared by other Federal agencies; and (10) any other areas set forth in the work assignment.

During the development of a health effects document, the contractor shall conduct literature reviews to augment the file of references provided by the EPA PO/WAM with other references.

3.1.5 The contractor shall prepare, evaluate, and revise health advisories for microorganisms. A health advisory provides information that public health officials use to help determine control priorities for pollutants in water as well as providing general information for the public. The contractor shall document the methodology, assumptions, and rationale used to prepare, evaluate, and revise a health advisory. EPA will make the final decision concerning any recommended health advisory based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

A health advisory for a microorganism shall address: (1) general information and properties of the microorganism; (2) occurrence and environmental fate and transport; (3) infectivity; (4) health effects in animals and humans; (5) treatability; (6) magnitude of infectious disease effects; and (7) any other areas set forth in the work assignment.

During the development of a health advisory, the contractor shall conduct literature reviews to augment the file of references provided by the EPA PO/WAM with other references.

3.1.6 The contractor shall provide technical support for the preparation, evaluation, and revision of hazard, exposure, or risk assessment/characterization techniques or methodologies for human health protection. This includes, among other things, providing technical support during the development of methodologies used to develop human health criteria for various water media. The contractor shall document the methodology, assumptions, and rationale used for this task.

EPA will make the final decision concerning any recommended technique or methodology based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.7 The contractor shall provide on a rapid response basis (as defined in 2.6) analyses of human health risk assessment guidelines for microorganisms, results of human health risk assessments, and treatment technology practices and procedures. This includes, among other things, analysis of the impact of criteria on sensitive populations, and analyses of dose response and infectivity data and exposure data.

3.1.8 The contractor shall prepare, evaluate, and revise technical guidance documents and position papers for microorganisms. These documents provide information on the principles for criteria development (e.g., minimum data requirements and exposure assumptions). The contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning any recommended technical guidance document based on

its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.9 The contractor shall evaluate "raw" data generated from an infectivity or epidemiology study. The raw data will be provided by the EPA PO/WAM. The evaluation shall include a complete description of the protocol used to gather the data; analyses of effects observed, including tabulation of all observations; evaluation of biological significance of endpoints according to EPA published guidelines or other technical documents; statistical analyses of the significance of observations; and conclusions as to existence of exposure-related effects and their implications for human health.

3.1.10 The contractor shall conduct appropriate statistical analyses of infectivity data, or epidemiological data, or exposure data, as specified in a work assignment. These analyses shall be completed in accordance with EPA published guidance or other technical documents.

3.1.11 The contractor shall provide analyses of food and water consumption patterns and associated exposure to infectious agents through foods for the U.S. population. These analyses shall include frequency and amount of specific foods consumed by sex, age, and geographical locations. Data to be analyzed shall include data from Federal data collection efforts, State collection efforts, and special studies. Similarly, the contractor shall provide analyses of exposure data from the Center for Disease Control National Health and Nutrition Examination Survey data base and the EPA National Human Exposure Assessment Survey data base, water quality data from U.S. Geological Survey and morbidity and mortality data on food and waterborne illnesses from available databases and other sources as deemed appropriate.

3.1.12 All of the above tasks and deliverables shall be completed in accordance with EPA published guidelines where available.

3.2 Sewage Sludge

3.2.1 The contractor shall provide technical support during the preparation, evaluation, and revision of procedures for selecting microbial pollutants-of-concern in sewage sludge that is used or disposed of, and shall provide technical support during the evaluation of those pollutants. The contractor shall document the methodology, assumptions, and rationale used for conducting this task. EPA will make the final decision concerning any recommended procedures to be used to select pollutants-of-concern and the evaluation of those pollutants based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.2.2 The contractor shall conduct exposure pathway risk assessments for microbial pollutants in sewage sludge applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator. The pathways evaluated for each use or disposal practice shall be the pathways evaluated for each use or disposal practice when the Standards for the Use or Disposal of Sewage Sludge (40 CFR Part 503) were developed, as well as other pathways specified in a work assignment. Results of these risk assessments will be used by EPA to develop limits for pollutants in sewage sludge.

3.2.3 The contractor shall provide technical support during the development of the rationales for the technology-based requirements in a sewage sludge use or disposal standard for pathogens and vector attraction reduction. The contractor shall document the methodology, assumptions, and rationales for this task (e.g.,

the rationale for the 38 percent volatile solids reduction requirement for vector attraction reduction). EPA will make the final decision concerning any recommended operational standard for pathogens and vector attraction reduction based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.2.4 The contractor shall prepare, evaluate, and revise technical support documents for a standard for the use or disposal of sewage sludge. These documents contain the rationales for the requirements (i.e., general requirements; pollutant limits; management practices; operational standards; and frequency of monitoring, record keeping, and reporting requirements) in a sewage sludge use or disposal standard (see 40 CFR Part 503). The contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning any recommended technical support document based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.3 Statistics Support

3.3.1 The contractor shall have statistical analyses capabilities to perform analyses of environmental data for microbial pollutants to derive descriptive or interpretative statistics.

3.3.2 The contractor shall conduct laboratory/field studies to support the development of water quality criteria, sewage sludge pollutant limits, and other program requirements, as specified in a work assignment.

3.3.3 The contractor shall perform statistical analyses of data from sampling to derive descriptive or interpretative statistics.

3.4 Administrative Record Support

The contractor shall provide data and documentation to be used by EPA in the analysis of technical issues and options for proposed and final regulations, as specified in a work assignment. Deliverables under this task include data summaries, technical reports, option papers, issue papers, and public and confidential records and files. The contractor shall describe and document the data gathering activities; display, characterize, and interpret the data and information collected; obtain copies of any references used; and describe all methodologies used. Written reports and corresponding records and files shall be prepared and organized, indexed, and cross-referenced in an administrative record for a proposed or final regulation so that the analyses and conclusions can be reproduced based on the information in the administrative record for a proposed or final regulation.

3.5 Rule making support

The contractor shall prepare Federal Register notices of EPA criteria and other regulatory documents and will index and summarize public comments on proposed regulations. Using information provided by EPA (i.e., typically public comments submitted in response to a proposed regulation and information collection requests), the contractor shall prepare an index of issues in the information provided by EPA, and cross reference those issues to the public comments. For technical issues assigned by the EPA PO/WAM, the contractor shall, based on knowledge of the appropriate rule making, prepare draft technical responses to the issues in the public comments including all relevant citations to the administrative record. EPA will review the draft technical responses, and prepare the final responses to the comments.

3.6 Preparation of outreach materials

3.6.1 The contractor shall develop outreach materials in support of the tasks in this PWS. These materials include brochures, presentation boards, slide shows, fact sheets, pamphlets, posters, videos, INTERNET layouts, and models. The materials shall be developed for use in media events (e.g., press releases). In addition, the contractor shall provide materials for distribution at presentations. All materials shall be provided in accordance with the limitations set for in the Section H clause titled "PRINTING (EPAAR 1552.208-70)." The contractor shall provide a draft of all materials for approval by the EPA PO/WAM, and shall prepare the final materials based on the EPA PO's/WAM's comments on the draft materials. For print products, the contractor shall provide a camera-ready copy or digital equivalent, and a disk copy in a disk format that enables the material to be loaded onto the INTERNET. This task shall be done only in direct support of the technical requirements in this PWS.

3.6.2 The contractor shall provide, when included in a work assignment, a complete and accurate translation of foreign language articles cited in a criteria document, a health advisory, or a technical guidance document. Translations shall be performed by experienced scientific translators well-versed in statistical, biomedical, microbiological, or epidemiological terminology. The contractor shall insure that there are no terminology or language usage ambiguities that make interpretation and analysis of the findings difficult. No translations shall be made without the written approval of the Project Officer.

3.7 Arranging and conducting workshops

The contractor shall provide support in arranging workshops, conferences, training sessions, and public meetings, and obtaining appropriate individuals to address various issues. Meeting support shall be limited in scope, and shall cover only those meetings required to address the requirements in this PWS. The contractor shall arrange travel only in accordance with the authority and limitations in the Section H clause titled "APPROVAL OF CONTRACTOR TRAVEL" (i.e., the use of contract funds to reimburse travel is strictly limited to logistical support for speakers, scientists, and experts who contribute directly to the requirements of a task in this PWS). The contractor shall support EPA by: (1) providing information for meeting agendas, including typing the agendas; (2) preparing drafts of technical information for use in preparing briefing materials; (3) identifying and inviting speakers and experts to participate in a workshop; (4) arranging for meeting space when Government space is not available; (5) arranging for the appropriate audio-visual equipment; (6) providing advance announcements, registration support, visual aid preparation, logistical support, case study preparation, interactive and role-playing activity development; and (7) preparing the minutes of the meeting, including the meeting results, for approval by the EPA WAM.

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment		Work Assignment Number B-03 <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:								
Contract Number EP-C-11-005	Contract Period 01/01/2011 To 12/31/2011 Base Option Period Number 3	Title of Work Assignment/SF Site Name Incorporation of new Technolog								
Contractor ICF INCORPORATED, L.L.C.		Specify Section and paragraph of Contract SOW 3.1, 3.3, 3.4, 3.6								
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input checked="" type="checkbox"/> Work Plan Approval		Period of Performance From 01/01/2011 To 12/31/2011								
Comments:										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
01/01/2011 To 12/31/2011										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated: 3/29/11		Cost/Fee: \$53,928.00				LOE: 390				
Cumulative Approved:		Cost/Fee: \$53,928.00				LOE: 390				
Work Assignment Manager Name Shamima Akhter						Branch/Mail Code:				
_____ (Signature) (Date)						Phone Number 202-566-0000				
Project Officer Name Shirley Harrison						FAX Number:				
_____ (Signature) (Date)						Branch/Mail Code:				
Other Agency Official Name						Phone Number: 202-566-1107				
_____ (Signature) (Date)						FAX Number:				
Contracting Official Name Donna Reinhart						Branch/Mail Code:				
_____ (Signature) (Date) 4/12/11						Phone Number: 513-487-2006				
						FAX Number:				

B-03

PERFORMANCE WORK STATEMENT

TECHNICAL AND REGULATORY SUPPORT FOR THE DEVELOPMENT OF CRITERIA FOR WATER MEDIA (MICROBIOLOGY EMPHASIS)

1.0 INTRODUCTION

1.1 Background

The mission of the United States Environmental Protection Agency's Office of Water (OW) under the Safe Drinking Water Act and the Clean Water Act includes protecting the public health from the adverse effects of microbial pollutants (e.g., chemicals and microorganisms) in media such as surface water, drinking water, wastewater, sewage sludge, and sediments. In fulfillment of this mission, OW's Office of Science and Technology (OST) develops effluent guidelines, human health criteria, implementation guidance for health advisories, maximum contaminate level goals, and limits for pollutants in various water media.

1.2 Purpose of Contract

The purpose of this contract is to provide technical and regulatory support services to the Health and Ecological Criteria Division (HECD) in OST for the development of human health criteria, implementation guidance for health advisories, maximum contaminate level goals, and pollutant limits concerning the adverse effects of microbial pollutants in media such as surface water, drinking water, wastewater, sewage sludge and sediments. This support includes direct activities and related activities such as conducting literature reviews, conducting risk assessments, performing statistical analyses, evaluating pollutants selected for review by the United States Environmental Protection Agency (EPA), assessing the potential impact of criteria on sensitive populations, preparing criteria documents, preparing health advisories, preparing technical guidance documents, preparing technical support documents for regulatory requirements, preparing the index of references for proposed and final regulations, summarizing comments on proposed regulations, and arranging and conducting workshops.

2.0 GENERAL TASKS

2.1 The contractor shall furnish all facilities, materials, equipment, and necessary professional, technical, and support personnel in support of the effort delineated below. The initial submission of all documents shall be in draft form for EPA review and comment. Required revisions will be provided to the contractor by EPA for incorporation into a final document.

2.2 The contractor shall possess or have access to appropriate equipment/software to perform mathematical modeling and statistical analyses in support of criteria development.

2.3 The contractor shall develop documents and data bases using EPA standard software (e.g., Word, Excel, and Lotus Notes), as specified in a work assignment. Software documentation shall be accessible to the EPA Work Assignment Manager (WAM) and other persons authorized by the EPA Project Officer (PO).

2.4 The contractor shall possess or have access to a laboratory that can analyze microbial pollutants (e.g., standard analytical methods for pathogens including molecular methods) in water media (e.g., wastewater, ground and or surface water, drinking water, sediment and sewage sludge), hereinafter referred to as water media, as specified in a work assignment. The contractor shall prepare a Quality Assurance Project Plan (QAPP) for work assignments that require environmental measurements or the use of secondary data.

2.5 The contractor shall provide information that will be used by EPA for quick responses and analyses of options, issues, and policy decisions as they relate to the tasks in this Performance Work Statement (PWS). Quick responses are those

that require completion in one to seven days, or as specified in a work assignment. EPA will review the results of all contractor analyses, and make a final determination with regard to program objectives and policy decisions.

2.6 The contractor shall comply with the requirements for studies and rulemaking records contained in authorities such as the Administrative Procedures Act, the Paperwork Reduction Act, the Clean Water Act, OMB Circular A-130 for management of Federal Information Resources, and the Federal Rules of Appellate Procedure (Rules 16 and 17, 28 U.S.C. Appendix).

2.7 The contractor shall perform the specific tasks in the PWS in accordance with the appropriate EPA risk assessment guidance and science policy guidance (e.g., guidance on the development of a human health criteria document), as indicated in a work assignment.

3.0 SPECIFIC TASKS

3.1 Preparation of Human Health Documents

3.1.1 The contractor shall prepare summaries of peer-reviewed literature on infectivity, and clinical and epidemiological endpoints, as specified in a work assignment. Each summary shall discuss the test protocol (e.g., endpoints measured; test species; the number, sex, and species of the control group and dosing group; the method, frequency, and duration of dosing), and shall evaluate the test protocol. Similarly, for epidemiological studies, the contractor shall evaluate the protocol, type of study (e.g., case-controlled, community, prospective, or retro prospective), analyses, and conclusions according to criteria as specified as appropriate by the WAM or CO.

3.1.2 The contractor shall prepare screening analyses that display and compare all available data for a microbial pollutant, and build on the summaries in subsection 3.1.1. If required by the work assignment, these analyses shall be presented as electronic data bases.

The contractor shall be able to develop figures, tables or other graphics to display the array of available data for a microbial pollutant building on the summaries in subsection 3.1.1. The requested data arrays may be used to assist in risk communication, facilitate the dose-response assessment and/or improve the transparency of health effects support documents.

The contractor shall collect data, prepare screening analyses and participate in the development of screening methodologies for microbial contaminants that will be useful in the development of future Critical Contaminant Lists (CCLs), prioritizing resources, and in identifying emerging contaminants.

3.1.3 The contractor shall be familiar with Federal and private exposure data bases and obtain them as needed for use in developing assessments. The contractor shall document the methodology, assumptions, and rationales used in the analyses.

EPA will make the final decision concerning any recommended finding based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.4 The contractor shall prepare, evaluate, and revise exposure and health effects documents. These documents provide information on the criteria that protect human health from exposure to a microorganism in water media. The contractor shall document the methodology, assumptions, and rationales used for this task. EPA will make the final decision concerning any recommended health effects document based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor

provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion

A health effects document for a microorganism shall address, as specified in a work assignment: (1) physical and biological properties of the microorganism; (2) occurrence and environmental fate and transport; (3) infectivity; (4) human exposure to the microorganism; (5) health effects for animals; (6) health effects for humans; (7) mechanisms of infectivity; (8) magnitude of infectious disease effects; (9) a summary of the results of health effects documents prepared by other Federal agencies; and (10) any other areas set forth in the work assignment.

During the development of a health effects document, the contractor shall conduct literature reviews to augment the file of references provided by the EPA PO/WAM with other references.

3.1.5 The contractor shall prepare, evaluate, and revise health advisories for microorganisms. A health advisory provides information that public health officials use to help determine control priorities for pollutants in water as well as providing general information for the public. The contractor shall document the methodology, assumptions, and rationale used to prepare, evaluate, and revise a health advisory. EPA will make the final decision concerning any recommended health advisory based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

A health advisory for a microorganism shall address: (1) general information and properties of the microorganism; (2) occurrence and environmental fate and transport; (3) infectivity; (4) health effects in animals and humans; (5) treatability; (6) magnitude of infectious disease effects; and (7) any other areas set forth in the work assignment.

During the development of a health advisory, the contractor shall conduct literature reviews to augment the file of references provided by the EPA PO/WAM with other references.

3.1.6 The contractor shall provide technical support for the preparation, evaluation, and revision of hazard, exposure, or risk assessment/characterization techniques or methodologies for human health protection. This includes, among other things, providing technical support during the development of methodologies used to develop human health criteria for various water media. The contractor shall document the methodology, assumptions, and rationale used for this task.

EPA will make the final decision concerning any recommended technique or methodology based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.7 The contractor shall provide on a rapid response basis (as defined in 2.6) analyses of human health risk assessment guidelines for microorganisms, results of human health risk assessments, and treatment technology practices and procedures. This includes, among other things, analysis of the impact of criteria on sensitive populations, and analyses of dose response and infectivity data and exposure data.

3.1.8 The contractor shall prepare, evaluate, and revise technical guidance documents and position papers for microorganisms. These documents provide information on the principles for criteria development (e.g., minimum data requirements and exposure assumptions). The contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning any recommended technical guidance document based on

its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.9 The contractor shall evaluate "raw" data generated from an infectivity or epidemiology study. The raw data will be provided by the EPA PO/WAM. The evaluation shall include a complete description of the protocol used to gather the data; analyses of effects observed, including tabulation of all observations; evaluation of biological significance of endpoints according to EPA published guidelines or other technical documents; statistical analyses of the significance of observations; and conclusions as to existence of exposure-related effects and their implications for human health.

3.1.10 The contractor shall conduct appropriate statistical analyses of infectivity data, or epidemiological data, or exposure data, as specified in a work assignment. These analyses shall be completed in accordance with EPA published guidance or other technical documents.

3.1.11 The contractor shall provide analyses of food and water consumption patterns and associated exposure to infectious agents through foods for the U.S. population. These analyses shall include frequency and amount of specific foods consumed by sex, age, and geographical locations. Data to be analyzed shall include data from Federal data collection efforts, State collection efforts, and special studies. Similarly, the contractor shall provide analyses of exposure data from the Center for Disease Control National Health and Nutrition Examination Survey data base and the EPA National Human Exposure Assessment Survey data base, water quality data from U.S. Geological Survey and morbidity and mortality data on food and waterborne illnesses from available databases and other sources as deemed appropriate.

3.1.12 All of the above tasks and deliverables shall be completed in accordance with EPA published guidelines where available.

3.2 Sewage Sludge

3.2.1 The contractor shall provide technical support during the preparation, evaluation, and revision of procedures for selecting microbial pollutants-of-concern in sewage sludge that is used or disposed of, and shall provide technical support during the evaluation of those pollutants. The contractor shall document the methodology, assumptions, and rationale used for conducting this task. EPA will make the final decision concerning any recommended procedures to be used to select pollutants-of-concern and the evaluation of those pollutants based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.2.2 The contractor shall conduct exposure pathway risk assessments for microbial pollutants in sewage sludge applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator. The pathways evaluated for each use or disposal practice shall be the pathways evaluated for each use or disposal practice when the Standards for the Use or Disposal of Sewage Sludge (40 CFR Part 503) were developed, as well as other pathways specified in a work assignment. Results of these risk assessments will be used by EPA to develop limits for pollutants in sewage sludge.

3.2.3 The contractor shall provide technical support during the development of the rationales for the technology-based requirements in a sewage sludge use or disposal standard for pathogens and vector attraction reduction. The contractor shall document the methodology, assumptions, and rationales for this task (e.g.,

the rationale for the 38 percent volatile solids reduction requirement for vector attraction reduction). EPA will make the final decision concerning any recommended operational standard for pathogens and vector attraction reduction based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.2.4 The contractor shall prepare, evaluate, and revise technical support documents for a standard for the use or disposal of sewage sludge. These documents contain the rationales for the requirements (i.e., general requirements; pollutant limits; management practices; operational standards; and frequency of monitoring, record keeping, and reporting requirements) in a sewage sludge use or disposal standard (see 40 CFR Part 503). The contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning any recommended technical support document based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.3 Statistics Support

3.3.1 The contractor shall have statistical analyses capabilities to perform analyses of environmental data for microbial pollutants to derive descriptive or interpretative statistics.

3.3.2 The contractor shall conduct laboratory/field studies to support the development of water quality criteria, sewage sludge pollutant limits, and other program requirements, as specified in a work assignment.

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The contractor shall provide data and documentation to be used by EPA in the analysis of technical issues and options for proposed and final regulations, as specified in a work assignment. Deliverables under this task include data summaries, technical reports, option papers, issue papers, and public and confidential records and files. The contractor shall describe and document the data gathering activities; display, characterize, and interpret the data and information collected; obtain copies of any references used; and describe all methodologies used. Written reports and corresponding records and files shall be prepared and organized, indexed, and cross-referenced in an administrative record for a proposed or final regulation so that the analyses and conclusions can be reproduced based on the information in the administrative record for a proposed or final regulation.

3.5 Rule making support

The contractor shall prepare Federal Register notices of EPA criteria and other regulatory documents and will index and summarize public comments on proposed regulations. Using information provided by EPA (i.e., typically public comments submitted in response to a proposed regulation and information collection requests), the contractor shall prepare an index of issues in the information provided by EPA, and cross reference those issues to the public comments. For technical issues assigned by the EPA PO/WAM, the contractor shall, based on knowledge of the appropriate rule making, prepare draft technical responses to the issues in the public comments including all relevant citations to the administrative record. EPA will review the draft technical responses, and prepare the final responses to the comments.

3.6 Preparation of outreach materials

3.6.1 The contractor shall develop outreach materials in support of the tasks in this PWS. These materials include brochures, presentation boards, slide shows, fact sheets, pamphlets, posters, videos, INTERNET layouts, and models. The materials shall be developed for use in media events (e.g., press releases). In addition, the contractor shall provide materials for distribution at presentations. All materials shall be provided in accordance with the limitations set for in the Section H clause titled "PRINTING (EPAAR 1552.208-70)." The contractor shall provide a draft of all materials for approval by the EPA PO/WAM, and shall prepare the final materials based on the EPA PO's/WAM's comments on the draft materials. For print products, the contractor shall provide a camera-ready copy or digital equivalent, and a disk copy in a disk format that enables the material to be loaded onto the INTERNET. This task shall be done only in direct support of the technical requirements in this PWS.

3.6.2 The contractor shall provide, when included in a work assignment, a complete and accurate translation of foreign language articles cited in a criteria document, a health advisory, or a technical guidance document. Translations shall be performed by experienced scientific translators well-versed in statistical, biomedical, microbiological, or epidemiological terminology. The contractor shall insure that there are no terminology or language usage ambiguities that make interpretation and analysis of the findings difficult. No translations shall be made without the written approval of the Project Officer.

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The contractor shall provide support in arranging workshops, conferences, training sessions, and public meetings, and obtaining appropriate individuals to address various issues. Meeting support shall be limited in scope, and shall cover only those meetings required to address the requirements in this PWS. The contractor shall arrange travel only in accordance with the authority and limitations in the Section H clause titled "APPROVAL OF CONTRACTOR TRAVEL" (i.e., the use of contract funds to reimburse travel is strictly limited to logistical support for speakers, scientists, and experts who contribute directly to the requirements of a task in this PWS). The contractor shall support EPA by: (1) providing information for meeting agendas, including typing the agendas; (2) preparing drafts of technical information for use in preparing briefing materials; (3) identifying and inviting speakers and experts to participate in a workshop; (4) arranging for meeting space when Government space is not available; (5) arranging for the appropriate audio-visual equipment; (6) providing advance announcements, registration support, visual aid preparation, logistical support, case study preparation, interactive and role-playing activity development; and (7) preparing the minutes of the meeting, including the meeting results, for approval by the EPA WAM.

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment		Work Assignment Number B-04								
		<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:								
Contract Number EP-C-11-005		Contract Period 01/01/2011 To 12/31/2011 Title of Work Assignment/SF Site Name QMRA Activities								
Contractor ICF INCORPORATED, L.L.C.		Specify Section and paragraph of Contract SOW 3.1, 3.3, 3.6								
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 03/11/2011 To 12/31/2011								
Comments:										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund <div style="text-align: center;">Accounting and Appropriations Data</div> <input checked="" type="checkbox"/> Non-Superfund </div>										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO (Max 2) <input type="checkbox"/>										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
01/01/2011 To 12/31/2011										
This Action:						1,840				
						1,840				
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:		Cost/Fee:		LOE:						
Cumulative Approved:		Cost/Fee:		LOE:						
Work Assignment Manager Name John Ravenscroft						Branch/Mail Code:				
						Phone Number 202-566-1101				
						FAX Number:				
(Signature) _____ (Date) _____						Branch/Mail Code:				
Project Officer Name Shirley Harrison						Phone Number 202-566-1107				
						FAX Number:				
(Signature) _____ (Date) _____						Branch/Mail Code:				
Other Agency Official Name Shirley Harrison						Phone Number 202-566-1107				
						FAX Number:				
(Signature) _____ (Date) _____						Branch/Mail Code:				
Contracting Official Name Donna Reinhart						Phone Number 513-487-2114				
						FAX Number:				
(Signature) _____ (Date) _____										

PERFORMANCE WORK STATEMENT

TECHNICAL AND REGULATORY SUPPORT FOR THE DEVELOPMENT OF CRITERIA FOR WATER MEDIA (MICROBIOLOGY EMPHASIS)

1.0 INTRODUCTION

1.1 Background

The mission of the United States Environmental Protection Agency's Office of Water (OW) under the Safe Drinking Water Act and the Clean Water Act includes protecting the public health from the adverse effects of microbial pollutants (e.g., chemicals and microorganisms) in media such as surface water, drinking water, wastewater, sewage sludge, and sediments. In fulfillment of this mission, OW's Office of Science and Technology (OST) develops effluent guidelines, human health criteria, implementation guidance for health advisories, maximum contaminate level goals, and limits for pollutants in various water media.

1.2 Purpose of Contract

The purpose of this contract is to provide technical and regulatory support services to the Health and Ecological Criteria Division (HECD) in OST for the development of human health criteria, implementation guidance for health advisories, maximum contaminate level goals, and pollutant limits concerning the adverse effects of microbial pollutants in media such as surface water, drinking water, wastewater, sewage sludge and sediments. This support includes direct activities and related activities such as conducting literature reviews, conducting risk assessments, performing statistical analyses, evaluating pollutants selected for review by the United States Environmental Protection Agency (EPA), assessing the potential impact of criteria on sensitive populations, preparing criteria documents, preparing health advisories, preparing technical guidance documents, preparing technical support documents for regulatory requirements, preparing the index of references for proposed and final regulations, summarizing comments on proposed regulations, and arranging and conducting workshops.

2.0 GENERAL TASKS

2.1 The contractor shall furnish all facilities, materials, equipment, and necessary professional, technical, and support personnel in support of the effort delineated below. The initial submission of all documents shall be in draft form for EPA review and comment. Required revisions will be provided to the contractor by EPA for incorporation into a final document.

2.2 The contractor shall possess or have access to appropriate equipment/software to perform mathematical modeling and statistical analyses in support of criteria development.

2.3 The contractor shall develop documents and data bases using EPA standard software (e.g., Word, Excel, and Lotus Notes), as specified in a work assignment. Software documentation shall be accessible to the EPA Work Assignment Manager (WAM) and other persons authorized by the EPA Project Officer (PO).

2.4 The contractor shall possess or have access to a laboratory that can analyze microbial pollutants (e.g., standard analytical methods for pathogens including molecular methods) in water media (e.g., wastewater, ground and or surface water, drinking water, sediment and sewage sludge), hereinafter referred to as water media, as specified in a work assignment. The contractor shall prepare a Quality Assurance Project Plan (QAPP) for work assignments that require environmental measurements or the use of secondary data.

2.5 The contractor shall provide information that will be used by EPA for quick responses and analyses of options, issues, and policy decisions as they relate to the tasks in this Performance Work Statement (PWS). Quick responses are those

that require completion in one to seven days, or as specified in a work assignment. EPA will review the results of all contractor analyses, and make a final determination with regard to program objectives and policy decisions.

2.6 The contractor shall comply with the requirements for studies and rulemaking records contained in authorities such as the Administrative Procedures Act, the Paperwork Reduction Act, the Clean Water Act, OMB Circular A-130 for management of Federal Information Resources, and the Federal Rules of Appellate Procedure (Rules 16 and 17, 28 U.S.C. Appendix).

2.7 The contractor shall perform the specific tasks in the PWS in accordance with the appropriate EPA risk assessment guidance and science policy guidance (e.g., guidance on the development of a human health criteria document), as indicated in a work assignment.

3.0 SPECIFIC TASKS

3.1 Preparation of Human Health Documents

3.1.1 The contractor shall prepare summaries of peer-reviewed literature on infectivity, and clinical and epidemiological endpoints, as specified in a work assignment. Each summary shall discuss the test protocol (e.g., endpoints measured; test species; the number, sex, and species of the control group and dosing group; the method, frequency, and duration of dosing), and shall evaluate the test protocol. Similarly, for epidemiological studies, the contractor shall evaluate the protocol, type of study (e.g., case-controlled, community, prospective, or retro prospective), analyses, and conclusions according to criteria as specified as appropriate by the WAM or CO.

3.1.2 The contractor shall prepare screening analyses that display and compare all available data for a microbial pollutant, and build on the summaries in subsection 3.1.1. If required by the work assignment, these analyses shall be presented as electronic data bases.

The contractor shall be able to develop figures, tables or other graphics to display the array of available data for a microbial pollutant building on the summaries in subsection 3.1.1. The requested data arrays may be used to assist in risk communication, facilitate the dose-response assessment and/or improve the transparency of health effects support documents.

The contractor shall collect data, prepare screening analyses and participate in the development of screening methodologies for microbial contaminants that will be useful in the development of future Critical Contaminant Lists (CCLs), prioritizing resources, and in identifying emerging contaminants.

3.1.3 The contractor shall be familiar with Federal and private exposure data bases and obtain them as needed for use in developing assessments. The contractor shall document the methodology, assumptions, and rationales used in the analyses.

EPA will make the final decision concerning any recommended finding based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.4 The contractor shall prepare, evaluate, and revise exposure and health effects documents. These documents provide information on the criteria that protect human health from exposure to a microorganism in water media. The contractor shall document the methodology, assumptions, and rationales used for this task. EPA will make the final decision concerning any recommended health effects document based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor

provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion

A health effects document for a microorganism shall address, as specified in a work assignment: (1) physical and biological properties of the microorganism; (2) occurrence and environmental fate and transport; (3) infectivity; (4) human exposure to the microorganism; (5) health effects for animals; (6) health effects for humans; (7) mechanisms of infectivity; (8) magnitude of infectious disease effects; (9) a summary of the results of health effects documents prepared by other Federal agencies; and (10) any other areas set forth in the work assignment.

During the development of a health effects document, the contractor shall conduct literature reviews to augment the file of references provided by the EPA PO/WAM with other references.

3.1.5 The contractor shall prepare, evaluate, and revise health advisories for microorganisms. A health advisory provides information that public health officials use to help determine control priorities for pollutants in water as well as providing general information for the public. The contractor shall document the methodology, assumptions, and rationale used to prepare, evaluate, and revise a health advisory. EPA will make the final decision concerning any recommended health advisory based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

A health advisory for a microorganism shall address: (1) general information and properties of the microorganism; (2) occurrence and environmental fate and transport; (3) infectivity; (4) health effects in animals and humans; (5) treatability; (6) magnitude of infectious disease effects; and (7) any other areas set forth in the work assignment.

During the development of a health advisory, the contractor shall conduct literature reviews to augment the file of references provided by the EPA PO/WAM with other references.

3.1.6 The contractor shall provide technical support for the preparation, evaluation, and revision of hazard, exposure, or risk assessment/characterization techniques or methodologies for human health protection. This includes, among other things, providing technical support during the development of methodologies used to develop human health criteria for various water media. The contractor shall document the methodology, assumptions, and rationale used for this task.

EPA will make the final decision concerning any recommended technique or methodology based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.7 The contractor shall provide on a rapid response basis (as defined in 2.6) analyses of human health risk assessment guidelines for microorganisms, results of human health risk assessments, and treatment technology practices and procedures. This includes, among other things, analysis of the impact of criteria on sensitive populations, and analyses of dose response and infectivity data and exposure data.

3.1.8 The contractor shall prepare, evaluate, and revise technical guidance documents and position papers for microorganisms. These documents provide information on the principles for criteria development (e.g., minimum data requirements and exposure assumptions). The contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning any recommended technical guidance document based on

its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.9 The contractor shall evaluate "raw" data generated from an infectivity or epidemiology study. The raw data will be provided by the EPA PO/WAM. The evaluation shall include a complete description of the protocol used to gather the data; analyses of effects observed, including tabulation of all observations; evaluation of biological significance of endpoints according to EPA published guidelines or other technical documents; statistical analyses of the significance of observations; and conclusions as to existence of exposure-related effects and their implications for human health.

3.1.10 The contractor shall conduct appropriate statistical analyses of infectivity data, or epidemiological data, or exposure data, as specified in a work assignment. These analyses shall be completed in accordance with EPA published guidance or other technical documents.

3.1.11 The contractor shall provide analyses of food and water consumption patterns and associated exposure to infectious agents through foods for the U.S. population. These analyses shall include frequency and amount of specific foods consumed by sex, age, and geographical locations. Data to be analyzed shall include data from Federal data collection efforts, State collection efforts, and special studies. Similarly, the contractor shall provide analyses of exposure data from the Center for Disease Control National Health and Nutrition Examination Survey data base and the EPA National Human Exposure Assessment Survey data base, water quality data from U.S. Geological Survey and morbidity and mortality data on food and waterborne illnesses from available databases and other sources as deemed appropriate.

3.1.12 All of the above tasks and deliverables shall be completed in accordance with EPA published guidelines where available.

3.2 Sewage Sludge

3.2.1 The contractor shall provide technical support during the preparation, evaluation, and revision of procedures for selecting microbial pollutants-of-concern in sewage sludge that is used or disposed of, and shall provide technical support during the evaluation of those pollutants. The contractor shall document the methodology, assumptions, and rationale used for conducting this task. EPA will make the final decision concerning any recommended procedures to be used to select pollutants-of-concern and the evaluation of those pollutants based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.2.2 The contractor shall conduct exposure pathway risk assessments for microbial pollutants in sewage sludge applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator. The pathways evaluated for each use or disposal practice shall be the pathways evaluated for each use or disposal practice when the Standards for the Use or Disposal of Sewage Sludge (40 CFR Part 503) were developed, as well as other pathways specified in a work assignment. Results of these risk assessments will be used by EPA to develop limits for pollutants in sewage sludge.

3.2.3 The contractor shall provide technical support during the development of the rationales for the technology-based requirements in a sewage sludge use or disposal standard for pathogens and vector attraction reduction. The contractor shall document the methodology, assumptions, and rationales for this task (e.g.,

the rationale for the 38 percent volatile solids reduction requirement for vector attraction reduction). EPA will make the final decision concerning any recommended operational standard for pathogens and vector attraction reduction based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.2.4 The contractor shall prepare, evaluate, and revise technical support documents for a standard for the use or disposal of sewage sludge. These documents contain the rationales for the requirements (i.e., general requirements; pollutant limits; management practices; operational standards; and frequency of monitoring, record keeping, and reporting requirements) in a sewage sludge use or disposal standard (see 40 CFR Part 503). The contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning any recommended technical support document based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.3 Statistics Support

3.3.1 The contractor shall have statistical analyses capabilities to perform analyses of environmental data for microbial pollutants to derive descriptive or interpretative statistics.

3.3.2 The contractor shall conduct laboratory/field studies to support the development of water quality criteria, sewage sludge pollutant limits, and other program requirements, as specified in a work assignment.

3.3.3 The contractor shall perform statistical analyses of data from sampling to derive descriptive or interpretive statistics.

3.4 Administrative Record Support

The contractor shall provide data and documentation to be used by EPA in the analysis of technical issues and options for proposed and final regulations, as specified in a work assignment. Deliverables under this task include data summaries, technical reports, option papers, issue papers, and public and confidential records and files. The contractor shall describe and document the data gathering activities; display, characterize, and interpret the data and information collected; obtain copies of any references used; and describe all methodologies used. Written reports and corresponding records and files shall be prepared and organized, indexed, and cross-referenced in an administrative record for a proposed or final regulation so that the analyses and conclusions can be reproduced based on the information in the administrative record for a proposed or final regulation.

3.5 Rule making support

The contractor shall prepare Federal Register notices of EPA criteria and other regulatory documents and will index and summarize public comments on proposed regulations. Using information provided by EPA (i.e., typically public comments submitted in response to a proposed regulation and information collection requests), the contractor shall prepare an index of issues in the information provided by EPA, and cross reference those issues to the public comments. For technical issues assigned by the EPA PO/WAM, the contractor shall, based on knowledge of the appropriate rule making, prepare draft technical responses to the issues in the public comments including all relevant citations to the administrative record. EPA will review the draft technical responses, and prepare the final responses to the comments.

3.6 Preparation of outreach materials

3.6.1 The contractor shall develop outreach materials in support of the tasks in this PWS. These materials include brochures, presentation boards, slide shows, fact sheets, pamphlets, posters, videos, INTERNET layouts, and models. The materials shall be developed for use in media events (e.g., press releases). In addition, the contractor shall provide materials for distribution at presentations. All materials shall be provided in accordance with the limitations set for in the Section H clause titled "PRINTING (EPAAR 1552.208-70)." The contractor shall provide a draft of all materials for approval by the EPA PO/WAM, and shall prepare the final materials based on the EPA PO's/WAM's comments on the draft materials. For print products, the contractor shall provide a camera-ready copy or digital equivalent, and a disk copy in a disk format that enables the material to be loaded onto the INTERNET. This task shall be done only in direct support of the technical requirements in this PWS.

3.6.2 The contractor shall provide, when included in a work assignment, a complete and accurate translation of foreign language articles cited in a criteria document, a health advisory, or a technical guidance document. Translations shall be performed by experienced scientific translators well-versed in statistical, biomedical, microbiological, or epidemiological terminology. The contractor shall insure that there are no terminology or language usage ambiguities that make interpretation and analysis of the findings difficult. No translations shall be made without the written approval of the Project Officer.

3.7 Arranging and conducting workshops

The contractor shall provide support in arranging workshops, conferences, training sessions, and public meetings, and obtaining appropriate individuals to address various issues. Meeting support shall be limited in scope, and shall cover only those meetings required to address the requirements in this PWS. The contractor shall arrange travel only in accordance with the authority and limitations in the Section H clause titled "APPROVAL OF CONTRACTOR TRAVEL" (i.e., the use of contract funds to reimburse travel is strictly limited to logistical support for speakers, scientists, and experts who contribute directly to the requirements of a task in this PWS). The contractor shall support EPA by: (1) providing information for meeting agendas, including typing the agendas; (2) preparing drafts of technical information for use in preparing briefing materials; (3) identifying and inviting speakers and experts to participate in a workshop; (4) arranging for meeting space when Government space is not available; (5) arranging for the appropriate audio-visual equipment; (6) providing advance announcements, registration support, visual aid preparation, logistical support, case study preparation, interactive and role-playing activity development; and (7) preparing the minutes of the meeting, including the meeting results, for approval by the EPA WAM.

EPAUnited States Environmental Protection Agency
Washington, DC 20460**Work Assignment**

Work Assignment Number

B-04

☐ Other☒ Amendment Number:

000001

Contract Number

EP-C-11-005

Contract Period 01/01/2011 To 12/31/2011

Base ☒

Option Period Number

Title of Work Assignment/SF Site Name

QMRA Activities

Contractor

ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

3.1, 3.3, 3.6

Purpose:

☐

Work Assignment

☐

Work Assignment Close-Out

☒

Work Assignment Amendment

☐

Incremental Funding

☐

Work Plan Approval

Period of Performance

From 03/11/2011 To 12/31/2011

Comments:

☐

Superfund

Accounting and Appropriations Data

☒

Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

SFO

(Max 2)

☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:

01/01/2011 To 12/31/2011

Cost/Fee:

LOE: 1,840

This Action:

925

Total:

2,765

Work Plan / Cost Estimate Approvals

Contractor WP Dated:

Cost/Fee:

LOE:

Cumulative Approved:

Cost/Fee:

LOE:

Work Assignment Manager Name John Ravenscroft

Branch/Mail Code:

Phone Number 202-566-1101

FAX Number:

(Signature)

(Date)

Project Officer Name Shirley Harrison

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

(Signature)

(Date)

Other Agency Official Name Shirley Harrison

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

(Signature)

(Date)

Contracting Official Name Donna Reinhart

Branch/Mail Code:

Phone Number: 513-487-2114

FAX Number:

(Signature)

(Date)

**Performance Work Statement
ICF Contract # EP-C-11-005
Work Assignment #B-04 Amendment 1**

Title: QMRA Activities to Support Criteria Development and Implementation

Period of Performance: Work Assignment Issuance through December 31, 2011

Work Assignment Manager: John Ravenscroft (Mail Code 4304T)
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

Alternate WAM: Sharon Nappier (Mail Code 4304T)
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Telephone #: 202-566-0740
E-mail: nappier.sharon@epa.gov

****Note:** No CBI data will be needed in the course of this work assignment.

LOE: 925

Contractor SOW: 3.1, 3.3, 3.6

Please note that this task list is a supplement to WA B-04; only the pertinent changes to that list (i.e., changes to existing tasks and the additional tasks) are denoted here. The original task list still applies (e.g., work plan and monthly progress reports).

Purpose: The purpose of this work assignment amendment is to add additional LOE hours and funding to accomplish the revisions under Task 1, 2.2, 4, 6 and 7.

Task 1: *Work plan, monthly progress reports and quality assurance* – same as original WA

Task Area 1.3 - Development of QMP and contract-level and project-specific QAPPs

Since the approval of B-04 workplan, the Agency has modified its requirements for the contract-level QAPP as specified in the original work assignment. The Contractor shall prepare a work assignment-specific QAPP inclusive of the scope of work found in the

original work assignment and this amendment. It will be crucial that the approved project-specific QAPP be updated to include the changes contained in this amendment, so the Contractor shall prioritize this task over the completion of the contract level QAPP as specified in the current workplan.

The Contractor shall refer to the other project-specific QAPPs prepared under this contract and incorporate the suggestions and requests made on those documents into this project-specific QAPP. Given the staffing plan from the original work plan, the Contractor shall include the following information in the project-specific QAPP for B-04:

- EPA staff/contractors/subcontractors responsible for approvals,
- EPA staff/contractors/subcontractors on the distribution list for work assignment-related tasks
- Sources of, and data quality objectives for, the secondary data used in the work assignment considered unique to the effort (i.e., not already covered in the generic QAPP) and analytical QA.
- QA relationships between prime and subcontractors/consultants specific to the work assignment; to include steps for data review, assessment and assurance for the specific arrangement reflected in that particular effort.

The Contractor shall submit a first draft of the contract-level QAPP by August 31, 2011 for consideration. The Contractor should anticipate that there will be multiple iterations of the contract-level QAPP before it is finally approved. The first draft will be informative for EPA's QA team and should be inclusive of all comments made to date on the project-level QAPPs.

Task Area 2: General Project Support

Task 2.2: Project communication support:

QMRA guidance: how to conduct a QMRA for ambient waters, data needs and analytical approaches. The QMRA process that is being developed under the current work assignment will need to be documented such that other, potentially unfamiliar, users could adopt this approach to develop site-specific criteria for surface waters in their state. The Contractor shall develop a guidance document for conducting QMRA, including a description of the QMRA process, a discussion of the data requirements, a listing of appropriate data to use in analyses (e.g., acceptable dose-response information, fecal source-specific information on pathogen and indicator organisms, etc.), a presentation of the analytical approaches (e.g., point estimates versus stochastic analyses), and suggestions for risk characterization to aid in Agency acceptance for site-specific criteria derivations using this approach.

This task is expected to be an iterative process that will require interaction with HECD's sister division: SHPD. Currently, the expectation is that implementation guidance will

follow the criteria publication by about one year. However, HECD may wish to reference QMRA formally in the criteria, so a guidance document may be needed prior to the implementation guidance.

The Contractor shall discuss with the EPA WAM ways to address the more immediate need of the criteria versus the longer term need of the implementation guidance. For example, one way to address this may be to generate two documents: one which discusses the QMRA approach in a general fashion; and, another which provides a detailed step-wise approach for conducting a QMRA.

The Contractor shall coordinate with the EPA WAM on a meeting schedule to specifically address this subtask. The Contractor shall attend two (2) meetings at EPA headquarters in Washington D.C. on this topic (during the period of performance) and participate in regular conference calls with the EPA WAM to detail progress on this task. The first in-person meeting shall be held for planning and scoping purposes and the second shall include a progress briefing for EPA personnel.

Agricultural Animal-impacted Runoff: preparation of report for external peer review.

The Agency has evaluated the potential for human illness from recreational exposure to freshwater impacted by fecal contamination from agricultural animal sources. This effort was summarized in the Critical Path Science Plan P4 report and shared by the Agency on the recreation water criteria development website. One of the developments occurring with the new criteria is the inclusion of and reference to QMRA as a flexibility tool for States to use in the derivation of site-specific criteria. While previous results for differential risks from different sources were published in the peer reviewed literature, those results did not include pathogen mobilization differences or the risk differential from mixed sources of fecal contamination (see task 4 in the original work assignment). The Agency will wish to have the latest information peer reviewed and published in order to provide strong support for the upcoming criteria document. The Contractor shall update the report detailed in this section so that it is suitable for peer review.

Task 4: *Relative QMRA refinement*

In the original workplan, this task was to begin based on technical direction which would consider the timing of this task relative to the priority of the other related QMRA tasks. This amendment will clarify that milestone schedule for this task.

The Contractor has been given a previous report that HECD generated containing the initial effort for considering fate and transport of pathogens and fecal indicators and also evaluating mixed sources. The Contractor shall utilize this draft report as a starting point for leveraging work on this task.

The Contractor will need to consider the overall goal for QMRA in the context of site-specific criteria for ambient waters as this task is conducted. The need to effectively

address the fate and transport of microbes from source to receptor, and identifying and delineating various sources of indicators relative to pathogens in a watershed, is crucial for developing a practical tool. As QMRA will be a core component of the recommended flexible approaches in the new criteria, attention will need to be given to the practical applications of this process.

The Contractor shall meet with the EPA WAM to discuss this task specifically. As the results of this task will directly inform the development of QMRA guidance, the Contractor shall develop a plan to coordinate these efforts. The milestone schedule should be reflective of this process. The Contractor shall include as part of the workplan for this amendment a proposed schedule for this task given this discussion.

Task 6: Children's Health, Sensitive Subpopulations, Alternate Study designs, and Environmental Justice evaluations

Task 6.1: QMRA approaches to evaluate risks to sensitive subpopulations and children's health.

The Contractor shall coordinate efforts under this subtask with the milestone schedule for B-07 as the information gathered in that work assignment will directly inform the efforts under this task. The Contractor shall propose a revised schedule for this task in the workplan based on that coordination.

Task 6.2: Alternate epidemiology study designs

Upon evaluation of the workplan for this task, it has become clear that the original intent of subtask 6.2c is being addressed in the work under task 5. Therefore, there does not appear to be a need to conduct a separate analysis evaluating ingestion volumes. However, as task 6.2 is being completed, the final report should utilize the task 5 analysis such that potential effects of ingestion volumes can be addressed within the context of different epi study designs.

Task 7: Chicago Area Waterways (CAWS) QMRA

There has been much interest from EPA Region 5 surrounding this task. Additional LOE and ODCs are being made available for this task in this amendment to cover the expanded needs related to the scope of the risk assessment.

The original workplan covered a screening-level assessment for the CAWS. This screening-level assessment, most likely conducted using point-estimates for the various parameters in the analysis, is intended to help inform the QMRA development process and also evaluate the utility of this approach to evaluate different exposure profiles and relative risks.

This expanded task will now consist of iteratively conducting a refinement of this screening-level assessment to include additional queries based on interest from Region 5. For example, the scope of the problem formulation and the risk characterization may be modified for a more practical interpretation of the risk analysis. The Contractor and EPA WAM shall coordinate with Region 5 to ensure that their questions will be covered by the expanded analysis. This may include using a stochastic approach with the risk analysis and would require additional effort and time on the part of the Contractor.

OST management will require an interim project update by mid-September. This update should include results of screening-level efforts, address how the results of the CAWS QMRA relate to the NEEAR study (or other primary contact epi study) results, and detail discussion with Region 5.

The Contractor should expect to visit EPA Region 5 once to help inform the development of the expanded problem formulation and the sanitary survey for the assessment. ODCs are being included to cover this visit.

Milestones:

Milestone	Date
Task 1.1 Workplan	Within 15 calendar days of receipt of WA
Task 1.3 Development of QAPPs	1 st Draft by August 31, 2011
	Other drafts TBD
Task 2.2	
QMRA Guidance	
1 st meeting for scoping guidance document	Mid August 2011
2 nd meeting: progress briefing	TBD
1 st draft of guidance	September 30, 2011
Agri. Animal Runoff report	
Discuss EPA comments on report with WAM	Mid-August 2011
Updated report for peer review (ready for mgmt approval)	Before end of September 2011
Final report for peer review	Within 2 weeks after EPA mgmt comments

Task 4	
Meeting for task coordination	Mid-August 2011
Contractor provides milestone schedule	Within 2 weeks after meeting with EPA (may require modification based on EPA comments)
Task 6	
QMRA to evaluate sensitive subpopulations	
Contractor provides updated schedule	Within 2 weeks of WP approval
Alternate epi study designs	Progress update by Oct. 31, 2011 Draft report by Dec. 15, 2011
Task 7 CAWS	
Screening level assessment	September 15, 2011
Refinements	
Region 5 visit, Sanitary survey	TBD
Contractor provides updated schedule	By September 30, 2011

EPAUnited States Environmental Protection Agency
Washington, DC 20460**Work Assignment**

Work Assignment Number

B-05

☐ Other ☐ Amendment Number:

Contract Number

EP-C-11-005

Contract Period 01/01/2011 To 12/31/2011

Base ☒

Option Period Number

Title of Work Assignment/SF Site Name

Trop. epi summary - indicators

Contractor

ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

3.1, 3.2

Purpose:



Work Assignment



Work Assignment Close-Out



Work Assignment Amendment



Incremental Funding



Work Plan Approval

Period of Performance

From 04/07/2011 To 12/31/2011

Comments:



Superfund

Accounting and Appropriations Data



Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

SFO
(Max 2)

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Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:

Cost/Fee:

LOE: 0

01/01/2011 To 12/31/2011

This Action:

136

Total:

136

Work Plan / Cost Estimate Approvals

Contractor WP Dated:

Cost/Fee:

LOE:

Cumulative Approved:

Cost/Fee:

LOE:

Work Assignment Manager Name Brendlyn Faison

Branch/Mail Code:

Phone Number 202-566-1311

FAX Number:

(Signature)

(Date)

Project Officer Name Shirley Harrison

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

(Signature)

(Date)

Other Agency Official Name Shirley Harrison

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

(Signature)

(Date)

Contracting Official Name Donna Reinhart

Branch/Mail Code:

Phone Number: 513-487-2114

FAX Number:

(Signature)

(Date)

PERFORMANCE WORK STATEMENT

TECHNICAL AND REGULATORY SUPPORT FOR THE DEVELOPMENT OF CRITERIA FOR WATER MEDIA (MICROBIOLOGY EMPHASIS)

1.0 INTRODUCTION

1.1 Background

The mission of the United States Environmental Protection Agency's Office of Water (OW) under the Safe Drinking Water Act and the Clean Water Act includes protecting the public health from the adverse effects of microbial pollutants (e.g., chemicals and microorganisms) in media such as surface water, drinking water, wastewater, sewage sludge, and sediments. In fulfillment of this mission, OW's Office of Science and Technology (OST) develops effluent guidelines, human health criteria, implementation guidance for health advisories, maximum contaminate level goals, and limits for pollutants in various water media.

1.2 Purpose of Contract

The purpose of this contract is to provide technical and regulatory support services to the Health and Ecological Criteria Division (HECD) in OST for the development of human health criteria, implementation guidance for health advisories, maximum contaminate level goals, and pollutant limits concerning the adverse effects of microbial pollutants in media such as surface water, drinking water, wastewater, sewage sludge and sediments. This support includes direct activities and related activities such as conducting literature reviews, conducting risk assessments, performing statistical analyses, evaluating pollutants selected for review by the United States Environmental Protection Agency (EPA), assessing the potential impact of criteria on sensitive populations, preparing criteria documents, preparing health advisories, preparing technical guidance documents, preparing technical support documents for regulatory requirements, preparing the index of references for proposed and final regulations, summarizing comments on proposed regulations, and arranging and conducting workshops.

2.0 GENERAL TASKS

2.1 The contractor shall furnish all facilities, materials, equipment, and necessary professional, technical, and support personnel in support of the effort delineated below. The initial submission of all documents shall be in draft form for EPA review and comment. Required revisions will be provided to the contractor by EPA for incorporation into a final document.

2.2 The contractor shall possess or have access to appropriate equipment/software to perform mathematical modeling and statistical analyses in support of criteria development.

2.3 The contractor shall develop documents and data bases using EPA standard software (e.g., Word, Excel, and Lotus Notes), as specified in a work assignment. Software documentation shall be accessible to the EPA Work Assignment Manager (WAM) and other persons authorized by the EPA Project Officer (PO).

2.4 The contractor shall possess or have access to a laboratory that can analyze microbial pollutants (e.g., standard analytical methods for pathogens including molecular methods) in water media (e.g., wastewater, ground and or surface water, drinking water, sediment and sewage sludge), hereinafter referred to as water media, as specified in a work assignment. The contractor shall prepare a Quality Assurance Project Plan (QAPP) for work assignments that require environmental measurements or the use of secondary data.

2.5 The contractor shall provide information that will be used by EPA for quick responses and analyses of options, issues, and policy decisions as they relate to the tasks in this Performance Work Statement (PWS). Quick responses are those

that require completion in one to seven days, or as specified in a work assignment. EPA will review the results of all contractor analyses, and make a final determination with regard to program objectives and policy decisions.

2.6 The contractor shall comply with the requirements for studies and rulemaking records contained in authorities such as the Administrative Procedures Act, the Paperwork Reduction Act, the Clean Water Act, OMB Circular A-130 for management of Federal Information Resources, and the Federal Rules of Appellate Procedure (Rules 16 and 17, 28 U.S.C. Appendix).

2.7 The contractor shall perform the specific tasks in the PWS in accordance with the appropriate EPA risk assessment guidance and science policy guidance (e.g., guidance on the development of a human health criteria document), as indicated in a work assignment.

3.0 SPECIFIC TASKS

3.1 Preparation of Human Health Documents

3.1.1 The contractor shall prepare summaries of peer-reviewed literature on infectivity, and clinical and epidemiological endpoints, as specified in a work assignment. Each summary shall discuss the test protocol (e.g., endpoints measured; test species; the number, sex, and species of the control group and dosing group; the method, frequency, and duration of dosing), and shall evaluate the test protocol. Similarly, for epidemiological studies, the contractor shall evaluate the protocol, type of study (e.g., case-controlled, community, prospective, or retro prospective), analyses, and conclusions according to criteria as specified as appropriate by the WAM or CO.

3.1.2 The contractor shall prepare screening analyses that display and compare all available data for a microbial pollutant, and build on the summaries in subsection 3.1.1. If required by the work assignment, these analyses shall be presented as electronic data bases.

The contractor shall be able to develop figures, tables or other graphics to display the array of available data for a microbial pollutant building on the summaries in subsection 3.1.1. The requested data arrays may be used to assist in risk communication, facilitate the dose-response assessment and/or improve the transparency of health effects support documents.

The contractor shall collect data, prepare screening analyses and participate in the development of screening methodologies for microbial contaminants that will be useful in the development of future Critical Contaminant Lists (CCLs), prioritizing resources, and in identifying emerging contaminants.

3.1.3 The contractor shall be familiar with Federal and private exposure data bases and obtain them as needed for use in developing assessments. The contractor shall document the methodology, assumptions, and rationales used in the analyses. EPA will make the final decision concerning any recommended finding based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.4 The contractor shall prepare, evaluate, and revise exposure and health effects documents. These documents provide information on the criteria that protect human health from exposure to a microorganism in water media. The contractor shall document the methodology, assumptions, and rationales used for this task. EPA will make the final decision concerning any recommended health effects document based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor

provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion

A health effects document for a microorganism shall address, as specified in a work assignment: (1) physical and biological properties of the microorganism; (2) occurrence and environmental fate and transport; (3) infectivity; (4) human exposure to the microorganism; (5) health effects for animals; (6) health effects for humans; (7) mechanisms of infectivity; (8) magnitude of infectious disease effects; (9) a summary of the results of health effects documents prepared by other Federal agencies; and (10) any other areas set forth in the work assignment.

During the development of a health effects document, the contractor shall conduct literature reviews to augment the file of references provided by the EPA PO/WAM with other references.

3.1.5 The contractor shall prepare, evaluate, and revise health advisories for microorganisms. A health advisory provides information that public health officials use to help determine control priorities for pollutants in water as well as providing general information for the public. The contractor shall document the methodology, assumptions, and rationale used to prepare, evaluate, and revise a health advisory. EPA will make the final decision concerning any recommended health advisory based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

A health advisory for a microorganism shall address: (1) general information and properties of the microorganism; (2) occurrence and environmental fate and transport; (3) infectivity; (4) health effects in animals and humans; (5) treatability; (6) magnitude of infectious disease effects; and (7) any other areas set forth in the work assignment.

During the development of a health advisory, the contractor shall conduct literature reviews to augment the file of references provided by the EPA PO/WAM with other references.

3.1.6 The contractor shall provide technical support for the preparation, evaluation, and revision of hazard, exposure, or risk assessment/characterization techniques or methodologies for human health protection. This includes, among other things, providing technical support during the development of methodologies used to develop human health criteria for various water media. The contractor shall document the methodology, assumptions, and rationale used for this task.

EPA will make the final decision concerning any recommended technique or methodology based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.7 The contractor shall provide on a rapid response basis (as defined in 2.6) analyses of human health risk assessment guidelines for microorganisms, results of human health risk assessments, and treatment technology practices and procedures. This includes, among other things, analysis of the impact of criteria on sensitive populations, and analyses of dose response and infectivity data and exposure data.

3.1.8 The contractor shall prepare, evaluate, and revise technical guidance documents and position papers for microorganisms. These documents provide information on the principles for criteria development (e.g., minimum data requirements and exposure assumptions). The contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning any recommended technical guidance document based on

its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.9 The contractor shall evaluate "raw" data generated from an infectivity or epidemiology study. The raw data will be provided by the EPA PO/WAM. The evaluation shall include a complete description of the protocol used to gather the data; analyses of effects observed, including tabulation of all observations; evaluation of biological significance of endpoints according to EPA published guidelines or other technical documents; statistical analyses of the significance of observations; and conclusions as to existence of exposure-related effects and their implications for human health.

3.1.10 The contractor shall conduct appropriate statistical analyses of infectivity data, or epidemiological data, or exposure data, as specified in a work assignment. These analyses shall be completed in accordance with EPA published guidance or other technical documents.

3.1.11 The contractor shall provide analyses of food and water consumption patterns and associated exposure to infectious agents through foods for the U.S. population. These analyses shall include frequency and amount of specific foods consumed by sex, age, and geographical locations. Data to be analyzed shall include data from Federal data collection efforts, State collection efforts, and special studies. Similarly, the contractor shall provide analyses of exposure data from the Center for Disease Control National Health and Nutrition Examination Survey data base and the EPA National Human Exposure Assessment Survey data base, water quality data from U.S. Geological Survey and morbidity and mortality data on food and waterborne illnesses from available databases and other sources as deemed appropriate.

3.1.12 All of the above tasks and deliverables shall be completed in accordance with EPA published guidelines where available.

3.2 Sewage Sludge

3.2.1 The contractor shall provide technical support during the preparation, evaluation, and revision of procedures for selecting microbial pollutants-of-concern in sewage sludge that is used or disposed of, and shall provide technical support during the evaluation of those pollutants. The contractor shall document the methodology, assumptions, and rationale used for conducting this task. EPA will make the final decision concerning any recommended procedures to be used to select pollutants-of-concern and the evaluation of those pollutants based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.2.2 The contractor shall conduct exposure pathway risk assessments for microbial pollutants in sewage sludge applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator. The pathways evaluated for each use or disposal practice shall be the pathways evaluated for each use or disposal practice when the Standards for the Use or Disposal of Sewage Sludge (40 CFR Part 503) were developed, as well as other pathways specified in a work assignment. Results of these risk assessments will be used by EPA to develop limits for pollutants in sewage sludge.

3.2.3 The contractor shall provide technical support during the development of the rationales for the technology-based requirements in a sewage sludge use or disposal standard for pathogens and vector attraction reduction. The contractor shall document the methodology, assumptions, and rationales for this task (e.g.,

the rationale for the 38 percent volatile solids reduction requirement for vector attraction reduction). EPA will make the final decision concerning any recommended operational standard for pathogens and vector attraction reduction based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.2.4 The contractor shall prepare, evaluate, and revise technical support documents for a standard for the use or disposal of sewage sludge. These documents contain the rationales for the requirements (i.e., general requirements; pollutant limits; management practices; operational standards; and frequency of monitoring, record keeping, and reporting requirements) in a sewage sludge use or disposal standard (see 40 CFR Part 503). The contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning any recommended technical support document based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.3 Statistics Support

3.3.1 The contractor shall have statistical analyses capabilities to perform analyses of environmental data for microbial pollutants to derive descriptive or interpretative statistics.

3.3.2 The contractor shall conduct laboratory/field studies to support the development of water quality criteria, sewage sludge pollutant limits, and other program requirements, as specified in a work assignment.

3.3.3 The contractor shall perform statistical analyses of data from sampling to derive descriptive or interpretive statistics.

3.4 Administrative Record Support

The contractor shall provide data and documentation to be used by EPA in the analysis of technical issues and options for proposed and final regulations, as specified in a work assignment. Deliverables under this task include data summaries, technical reports, option papers, issue papers, and public and confidential records and files. The contractor shall describe and document the data gathering activities; display, characterize, and interpret the data and information collected; obtain copies of any references used; and describe all methodologies used. Written reports and corresponding records and files shall be prepared and organized, indexed, and cross-referenced in an administrative record for a proposed or final regulation so that the analyses and conclusions can be reproduced based on the information in the administrative record for a proposed or final regulation.

3.5 Rule making support

The contractor shall prepare Federal Register notices of EPA criteria and other regulatory documents and will index and summarize public comments on proposed regulations. Using information provided by EPA (i.e., typically public comments submitted in response to a proposed regulation and information collection requests), the contractor shall prepare an index of issues in the information provided by EPA, and cross reference those issues to the public comments. For technical issues assigned by the EPA PO/WAM, the contractor shall, based on knowledge of the appropriate rule making, prepare draft technical responses to the issues in the public comments including all relevant citations to the administrative record. EPA will review the draft technical responses, and prepare the final responses to the comments.

3.6 Preparation of outreach materials

3.6.1 The contractor shall develop outreach materials in support of the tasks in this PWS. These materials include brochures, presentation boards, slide shows, fact sheets, pamphlets, posters, videos, INTERNET layouts, and models. The materials shall be developed for use in media events (e.g., press releases). In addition, the contractor shall provide materials for distribution at presentations. All materials shall be provided in accordance with the limitations set for in the Section H clause titled "PRINTING (EPAAR 1552.208-70)." The contractor shall provide a draft of all materials for approval by the EPA PO/WAM, and shall prepare the final materials based on the EPA PO's/WAM's comments on the draft materials. For print products, the contractor shall provide a camera-ready copy or digital equivalent, and a disk copy in a disk format that enables the material to be loaded onto the INTERNET. This task shall be done only in direct support of the technical requirements in this PWS.

3.6.2 The contractor shall provide, when included in a work assignment, a complete and accurate translation of foreign language articles cited in a criteria document, a health advisory, or a technical guidance document. Translations shall be performed by experienced scientific translators well-versed in statistical, biomedical, microbiological, or epidemiological terminology. The contractor shall insure that there are no terminology or language usage ambiguities that make interpretation and analysis of the findings difficult. No translations shall be made without the written approval of the Project Officer.

3.7 Arranging and conducting workshops

The contractor shall provide support in arranging workshops, conferences, training sessions, and public meetings, and obtaining appropriate individuals to address various issues. Meeting support shall be limited in scope, and shall cover only those meetings required to address the requirements in this PWS. The contractor shall arrange travel only in accordance with the authority and limitations in the Section H clause titled "APPROVAL OF CONTRACTOR TRAVEL" (i.e., the use of contract funds to reimburse travel is strictly limited to logistical support for speakers, scientists, and experts who contribute directly to the requirements of a task in this PWS). The contractor shall support EPA by: (1) providing information for meeting agendas, including typing the agendas; (2) preparing drafts of technical information for use in preparing briefing materials; (3) identifying and inviting speakers and experts to participate in a workshop; (4) arranging for meeting space when Government space is not available; (5) arranging for the appropriate audio-visual equipment; (6) providing advance announcements, registration support, visual aid preparation, logistical support, case study preparation, interactive and role-playing activity development; and (7) preparing the minutes of the meeting, including the meeting results, for approval by the EPA WAM.

EPAUnited States Environmental Protection Agency
Washington, DC 20460**Work Assignment**

Work Assignment Number

B-06

☐ Other ☐ Amendment Number:

Contract Number

EP-C-11-005

Contract Period 01/01/2011 To 12/31/2011

Base ☒

Option Period Number

Title of Work Assignment/SF Site Name

qPCR performance

Contractor

ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

3.1, 3.2

Purpose:



Work Assignment



Work Assignment Close-Out



Work Assignment Amendment



Incremental Funding



Work Plan Approval

Period of Performance

From 04/26/2011 To 12/31/2011

Comments:



Superfund

Accounting and Appropriations Data



Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

SFO

(Max 2)

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Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:

01/01/2011 To 12/31/2011

Cost/Fee:

LOE: 0

This Action:

322

Total:

322

Work Plan / Cost Estimate Approvals

Contractor WP Dated:

Cost/Fee:

LOE:

Cumulative Approved:

Cost/Fee:

LOE:

Work Assignment Manager Name Brendlyn Faison

Branch/Mail Code:

Phone Number 202-566-1311

FAX Number:

(Signature)

(Date)

Project Officer Name Shirley Harrison

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

(Signature)

(Date)

Other Agency Official Name Shirley Harrison

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

(Signature)

(Date)

Contracting Official Name Donna Reinhart

Branch/Mail Code:

Phone Number: 513-487-2114

FAX Number:

(Signature)

(Date)

PERFORMANCE WORK STATEMENT

TECHNICAL AND REGULATORY SUPPORT FOR THE DEVELOPMENT OF CRITERIA FOR WATER MEDIA (MICROBIOLOGY EMPHASIS)

1.0 INTRODUCTION

1.1 Background

The mission of the United States Environmental Protection Agency's Office of Water (OW) under the Safe Drinking Water Act and the Clean Water Act includes protecting the public health from the adverse effects of microbial pollutants (e.g., chemicals and microorganisms) in media such as surface water, drinking water, wastewater, sewage sludge, and sediments. In fulfillment of this mission, OW's Office of Science and Technology (OST) develops effluent guidelines, human health criteria, implementation guidance for health advisories, maximum contaminate level goals, and limits for pollutants in various water media.

1.2 Purpose of Contract

The purpose of this contract is to provide technical and regulatory support services to the Health and Ecological Criteria Division (HECD) in OST for the development of human health criteria, implementation guidance for health advisories, maximum contaminate level goals, and pollutant limits concerning the adverse effects of microbial pollutants in media such as surface water, drinking water, wastewater, sewage sludge and sediments. This support includes direct activities and related activities such as conducting literature reviews, conducting risk assessments, performing statistical analyses, evaluating pollutants selected for review by the United States Environmental Protection Agency (EPA), assessing the potential impact of criteria on sensitive populations, preparing criteria documents, preparing health advisories, preparing technical guidance documents, preparing technical support documents for regulatory requirements, preparing the index of references for proposed and final regulations, summarizing comments on proposed regulations, and arranging and conducting workshops.

2.0 GENERAL TASKS

2.1 The contractor shall furnish all facilities, materials, equipment, and necessary professional, technical, and support personnel in support of the effort delineated below. The initial submission of all documents shall be in draft form for EPA review and comment. Required revisions will be provided to the contractor by EPA for incorporation into a final document.

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2.4 The contractor shall possess or have access to a laboratory that can analyze microbial pollutants (e.g., standard analytical methods for pathogens including molecular methods) in water media (e.g., wastewater, ground and or surface water, drinking water, sediment and sewage sludge), hereinafter referred to as water media, as specified in a work assignment. The contractor shall prepare a Quality Assurance Project Plan (QAPP) for work assignments that require environmental measurements or the use of secondary data.

2.5 The contractor shall provide information that will be used by EPA for quick responses and analyses of options, issues, and policy decisions as they relate to the tasks in this Performance Work Statement (PWS). Quick responses are those

that require completion in one to seven days, or as specified in a work assignment. EPA will review the results of all contractor analyses, and make a final determination with regard to program objectives and policy decisions.

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2.7 The contractor shall perform the specific tasks in the PWS in accordance with the appropriate EPA risk assessment guidance and science policy guidance (e.g., guidance on the development of a human health criteria document), as indicated in a work assignment.

3.0 SPECIFIC TASKS

3.1 Preparation of Human Health Documents

3.1.1 The contractor shall prepare summaries of peer-reviewed literature on infectivity, and clinical and epidemiological endpoints, as specified in a work assignment. Each summary shall discuss the test protocol (e.g., endpoints measured; test species; the number, sex, and species of the control group and dosing group; the method, frequency, and duration of dosing), and shall evaluate the test protocol. Similarly, for epidemiological studies, the contractor shall evaluate the protocol, type of study (e.g., case-controlled, community, prospective, or retro prospective), analyses, and conclusions according to criteria as specified as appropriate by the WAM or CO.

3.1.2 The contractor shall prepare screening analyses that display and compare all available data for a microbial pollutant, and build on the summaries in subsection 3.1.1. If required by the work assignment, these analyses shall be presented as electronic data bases.

The contractor shall be able to develop figures, tables or other graphics to display the array of available data for a microbial pollutant building on the summaries in subsection 3.1.1. The requested data arrays may be used to assist in risk communication, facilitate the dose-response assessment and/or improve the transparency of health effects support documents.

The contractor shall collect data, prepare screening analyses and participate in the development of screening methodologies for microbial contaminants that will be useful in the development of future Critical Contaminant Lists (CCLs), prioritizing resources, and in identifying emerging contaminants.

3.1.3 The contractor shall be familiar with Federal and private exposure data bases and obtain them as needed for use in developing assessments. The contractor shall document the methodology, assumptions, and rationales used in the analyses.

EPA will make the final decision concerning any recommended finding based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.4 The contractor shall prepare, evaluate, and revise exposure and health effects documents. These documents provide information on the criteria that protect human health from exposure to a microorganism in water media. The contractor shall document the methodology, assumptions, and rationales used for this task. EPA will make the final decision concerning any recommended health effects document based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor

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A health effects document for a microorganism shall address, as specified in a work assignment: (1) physical and biological properties of the microorganism; (2) occurrence and environmental fate and transport; (3) infectivity; (4) human exposure to the microorganism; (5) health effects for animals; (6) health effects for humans; (7) mechanisms of infectivity; (8) magnitude of infectious disease effects; (9) a summary of the results of health effects documents prepared by other Federal agencies; and (10) any other areas set forth in the work assignment.

During the development of a health effects document, the contractor shall conduct literature reviews to augment the file of references provided by the EPA PO/WAM with other references.

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A health advisory for a microorganism shall address: (1) general information and properties of the microorganism; (2) occurrence and environmental fate and transport; (3) infectivity; (4) health effects in animals and humans; (5) treatability; (6) magnitude of infectious disease effects; and (7) any other areas set forth in the work assignment.

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3.1.6 The contractor shall provide technical support for the preparation, evaluation, and revision of hazard, exposure, or risk assessment/characterization techniques or methodologies for human health protection. This includes, among other things, providing technical support during the development of methodologies used to develop human health criteria for various water media. The contractor shall document the methodology, assumptions, and rationale used for this task.

EPA will make the final decision concerning any recommended technique or methodology based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.7 The contractor shall provide on a rapid response basis (as defined in 2.6) analyses of human health risk assessment guidelines for microorganisms, results of human health risk assessments, and treatment technology practices and procedures. This includes, among other things, analysis of the impact of criteria on sensitive populations, and analyses of dose response and infectivity data and exposure data.

3.1.8 The contractor shall prepare, evaluate, and revise technical guidance documents and position papers for microorganisms. These documents provide information on the principles for criteria development (e.g., minimum data requirements and exposure assumptions). The contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning any recommended technical guidance document based on

its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.9 The contractor shall evaluate "raw" data generated from an infectivity or epidemiology study. The raw data will be provided by the EPA PO/WAM. The evaluation shall include a complete description of the protocol used to gather the data; analyses of effects observed, including tabulation of all observations; evaluation of biological significance of endpoints according to EPA published guidelines or other technical documents; statistical analyses of the significance of observations; and conclusions as to existence of exposure-related effects and their implications for human health.

3.1.10 The contractor shall conduct appropriate statistical analyses of infectivity data, or epidemiological data, or exposure data, as specified in a work assignment. These analyses shall be completed in accordance with EPA published guidance or other technical documents.

3.1.11 The contractor shall provide analyses of food and water consumption patterns and associated exposure to infectious agents through foods for the U.S. population. These analyses shall include frequency and amount of specific foods consumed by sex, age, and geographical locations. Data to be analyzed shall include data from Federal data collection efforts, State collection efforts, and special studies. Similarly, the contractor shall provide analyses of exposure data from the Center for Disease Control National Health and Nutrition Examination Survey data base and the EPA National Human Exposure Assessment Survey data base, water quality data from U.S. Geological Survey and morbidity and mortality data on food and waterborne illnesses from available databases and other sources as deemed appropriate.

3.1.12 All of the above tasks and deliverables shall be completed in accordance with EPA published guidelines where available.

3.2 Sewage Sludge

3.2.1 The contractor shall provide technical support during the preparation, evaluation, and revision of procedures for selecting microbial pollutants-of-concern in sewage sludge that is used or disposed of, and shall provide technical support during the evaluation of those pollutants. The contractor shall document the methodology, assumptions, and rationale used for conducting this task. EPA will make the final decision concerning any recommended procedures to be used to select pollutants-of-concern and the evaluation of those pollutants based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.2.2 The contractor shall conduct exposure pathway risk assessments for microbial pollutants in sewage sludge applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator. The pathways evaluated for each use or disposal practice shall be the pathways evaluated for each use or disposal practice when the Standards for the Use or Disposal of Sewage Sludge (40 CFR Part 503) were developed, as well as other pathways specified in a work assignment. Results of these risk assessments will be used by EPA to develop limits for pollutants in sewage sludge.

3.2.3 The contractor shall provide technical support during the development of the rationales for the technology-based requirements in a sewage sludge use or disposal standard for pathogens and vector attraction reduction. The contractor shall document the methodology, assumptions, and rationales for this task (e.g.,

the rationale for the 38 percent volatile solids reduction requirement for vector attraction reduction). EPA will make the final decision concerning any recommended operational standard for pathogens and vector attraction reduction based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.2.4 The contractor shall prepare, evaluate, and revise technical support documents for a standard for the use or disposal of sewage sludge. These documents contain the rationales for the requirements (i.e., general requirements; pollutant limits; management practices; operational standards; and frequency of monitoring, record keeping, and reporting requirements) in a sewage sludge use or disposal standard (see 40 CFR Part 503). The contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning any recommended technical support document based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.3 Statistics Support

3.3.1 The contractor shall have statistical analyses capabilities to perform analyses of environmental data for microbial pollutants to derive descriptive or interpretative statistics.

3.3.2 The contractor shall conduct laboratory/field studies to support the development of water quality criteria, sewage sludge pollutant limits, and other program requirements, as specified in a work assignment.

3.3.3 The contractor shall perform statistical analyses of data from sampling to derive descriptive or interpretative statistics.

3.4 Administrative Record Support

The contractor shall provide data and documentation to be used by EPA in the analysis of technical issues and options for proposed and final regulations, as specified in a work assignment. Deliverables under this task include data summaries, technical reports, option papers, issue papers, and public and confidential records and files. The contractor shall describe and document the data gathering activities; display, characterize, and interpret the data and information collected; obtain copies of any references used; and describe all methodologies used. Written reports and corresponding records and files shall be prepared and organized, indexed, and cross-referenced in an administrative record for a proposed or final regulation so that the analyses and conclusions can be reproduced based on the information in the administrative record for a proposed or final regulation.

3.5 Rule making support

The contractor shall prepare Federal Register notices of EPA criteria and other regulatory documents and will index and summarize public comments on proposed regulations. Using information provided by EPA (i.e., typically public comments submitted in response to a proposed regulation and information collection requests), the contractor shall prepare an index of issues in the information provided by EPA, and cross reference those issues to the public comments. For technical issues assigned by the EPA PO/WAM, the contractor shall, based on knowledge of the appropriate rule making, prepare draft technical responses to the issues in the public comments including all relevant citations to the administrative record. EPA will review the draft technical responses, and prepare the final responses to the comments.

3.6 Preparation of outreach materials

3.6.1 The contractor shall develop outreach materials in support of the tasks in this PWS. These materials include brochures, presentation boards, slide shows, fact sheets, pamphlets, posters, videos, INTERNET layouts, and models. The materials shall be developed for use in media events (e.g., press releases). In addition, the contractor shall provide materials for distribution at presentations. All materials shall be provided in accordance with the limitations set for in the Section H clause titled "PRINTING (EPAAR 1552.208-70)." The contractor shall provide a draft of all materials for approval by the EPA PO/WAM, and shall prepare the final materials based on the EPA PO's/WAM's comments on the draft materials. For print products, the contractor shall provide a camera-ready copy or digital equivalent, and a disk copy in a disk format that enables the material to be loaded onto the INTERNET. This task shall be done only in direct support of the technical requirements in this PWS.

3.6.2 The contractor shall provide, when included in a work assignment, a complete and accurate translation of foreign language articles cited in a criteria document, a health advisory, or a technical guidance document. Translations shall be performed by experienced scientific translators well-versed in statistical, biomedical, microbiological, or epidemiological terminology. The contractor shall insure that there are no terminology or language usage ambiguities that make interpretation and analysis of the findings difficult. No translations shall be made without the written approval of the Project Officer.

3.7 Arranging and conducting workshops

The contractor shall provide support in arranging workshops, conferences, training sessions, and public meetings, and obtaining appropriate individuals to address various issues. Meeting support shall be limited in scope, and shall cover only those meetings required to address the requirements in this PWS. The contractor shall arrange travel only in accordance with the authority and limitations in the Section H clause titled "APPROVAL OF CONTRACTOR TRAVEL" (i.e., the use of contract funds to reimburse travel is strictly limited to logistical support for speakers, scientists, and experts who contribute directly to the requirements of a task in this PWS). The contractor shall support EPA by: (1) providing information for meeting agendas, including typing the agendas; (2) preparing drafts of technical information for use in preparing briefing materials; (3) identifying and inviting speakers and experts to participate in a workshop; (4) arranging for meeting space when Government space is not available; (5) arranging for the appropriate audio-visual equipment; (6) providing advance announcements, registration support, visual aid preparation, logistical support, case study preparation, interactive and role-playing activity development; and (7) preparing the minutes of the meeting, including the meeting results, for approval by the EPA WAM.

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment		Work Assignment Number B-07								
		<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:								
Contract Number EP-C-11-005		Contract Period 01/01/2011 To 12/31/2011 Base <input checked="" type="checkbox"/> Option Period Number								
Title of Work Assignment/SF Site Name Children's risks from fecal co										
Contractor ICF INCORPORATED, L.L.C.		Specify Section and paragraph of Contract SOW 3.1, 3.3, 3.6								
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 06/13/2011 To 12/31/2011								
Comments:										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO (Max 2) <input type="checkbox"/>										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:		0				
01/01/2011 To 12/31/2011										
This Action:						880				
						880				
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:		Cost/Fee:		LOE:						
Cumulative Approved:		Cost/Fee:		LOE:						
Work Assignment Manager Name John Ravenscroft _____ (Signature) (Date)						Branch/Mail Code: Phone Number 202-566-1101 FAX Number:				
Project Officer Name Shirley Harrison _____ (Signature) (Date)						Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:				
Other Agency Official Name Shirley Harrison _____ (Signature) (Date)						Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:				
Contracting Official Name Donna Reinhart _____ (Signature) (Date)						Branch/Mail Code: Phone Number: 513-487-2114 FAX Number:				

PERFORMANCE WORK STATEMENT

TECHNICAL AND REGULATORY SUPPORT FOR THE DEVELOPMENT OF CRITERIA FOR WATER MEDIA (MICROBIOLOGY EMPHASIS)

1.0 INTRODUCTION

1.1 Background

The mission of the United States Environmental Protection Agency's Office of Water (OW) under the Safe Drinking Water Act and the Clean Water Act includes protecting the public health from the adverse effects of microbial pollutants (e.g., chemicals and microorganisms) in media such as surface water, drinking water, wastewater, sewage sludge, and sediments. In fulfillment of this mission, OW's Office of Science and Technology (OST) develops effluent guidelines, human health criteria, implementation guidance for health advisories, maximum contaminate level goals, and limits for pollutants in various water media.

1.2 Purpose of Contract

The purpose of this contract is to provide technical and regulatory support services to the Health and Ecological Criteria Division (HECD) in OST for the development of human health criteria, implementation guidance for health advisories, maximum contaminate level goals, and pollutant limits concerning the adverse effects of microbial pollutants in media such as surface water, drinking water, wastewater, sewage sludge and sediments. This support includes direct activities and related activities such as conducting literature reviews, conducting risk assessments, performing statistical analyses, evaluating pollutants selected for review by the United States Environmental Protection Agency (EPA), assessing the potential impact of criteria on sensitive populations, preparing criteria documents, preparing health advisories, preparing technical guidance documents, preparing technical support documents for regulatory requirements, preparing the index of references for proposed and final regulations, summarizing comments on proposed regulations, and arranging and conducting workshops.

2.0 GENERAL TASKS

2.1 The contractor shall furnish all facilities, materials, equipment, and necessary professional, technical, and support personnel in support of the effort delineated below. The initial submission of all documents shall be in draft form for EPA review and comment. Required revisions will be provided to the contractor by EPA for incorporation into a final document.

2.2 The contractor shall possess or have access to appropriate equipment/software to perform mathematical modeling and statistical analyses in support of criteria development.

2.3 The contractor shall develop documents and data bases using EPA standard software (e.g., Word, Excel, and Lotus Notes), as specified in a work assignment. Software documentation shall be accessible to the EPA Work Assignment Manager (WAM) and other persons authorized by the EPA Project Officer (PO).

2.4 The contractor shall possess or have access to a laboratory that can analyze microbial pollutants (e.g., standard analytical methods for pathogens including molecular methods) in water media (e.g., wastewater, ground and or surface water, drinking water, sediment and sewage sludge), hereinafter referred to as water media, as specified in a work assignment. The contractor shall prepare a Quality Assurance Project Plan (QAPP) for work assignments that require environmental measurements or the use of secondary data.

2.5 The contractor shall provide information that will be used by EPA for quick responses and analyses of options, issues, and policy decisions as they relate to the tasks in this Performance Work Statement (PWS). Quick responses are those

that require completion in one to seven days, or as specified in a work assignment. EPA will review the results of all contractor analyses, and make a final determination with regard to program objectives and policy decisions.

2.6 The contractor shall comply with the requirements for studies and rulemaking records contained in authorities such as the Administrative Procedures Act, the Paperwork Reduction Act, the Clean Water Act, OMB Circular A-130 for management of Federal Information Resources, and the Federal Rules of Appellate Procedure (Rules 16 and 17, 28 U.S.C. Appendix).

2.7 The contractor shall perform the specific tasks in the PWS in accordance with the appropriate EPA risk assessment guidance and science policy guidance (e.g., guidance on the development of a human health criteria document), as indicated in a work assignment.

3.0 SPECIFIC TASKS

3.1 Preparation of Human Health Documents

3.1.1 The contractor shall prepare summaries of peer-reviewed literature on infectivity, and clinical and epidemiological endpoints, as specified in a work assignment. Each summary shall discuss the test protocol (e.g., endpoints measured; test species; the number, sex, and species of the control group and dosing group; the method, frequency, and duration of dosing), and shall evaluate the test protocol. Similarly, for epidemiological studies, the contractor shall evaluate the protocol, type of study (e.g., case-controlled, community, prospective, or retro prospective), analyses, and conclusions according to criteria as specified as appropriate by the WAM or CO.

3.1.2 The contractor shall prepare screening analyses that display and compare all available data for a microbial pollutant, and build on the summaries in subsection 3.1.1. If required by the work assignment, these analyses shall be presented as electronic data bases.

The contractor shall be able to develop figures, tables or other graphics to display the array of available data for a microbial pollutant building on the summaries in subsection 3.1.1. The requested data arrays may be used to assist in risk communication, facilitate the dose-response assessment and/or improve the transparency of health effects support documents.

The contractor shall collect data, prepare screening analyses and participate in the development of screening methodologies for microbial contaminants that will be useful in the development of future Critical Contaminant Lists (CCLs), prioritizing resources, and in identifying emerging contaminants.

3.1.3 The contractor shall be familiar with Federal and private exposure data bases and obtain them as needed for use in developing assessments. The contractor shall document the methodology, assumptions, and rationales used in the analyses.

EPA will make the final decision concerning any recommended finding based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.4 The contractor shall prepare, evaluate, and revise exposure and health effects documents. These documents provide information on the criteria that protect human health from exposure to a microorganism in water media. The contractor shall document the methodology, assumptions, and rationales used for this task. EPA will make the final decision concerning any recommended health effects document based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor

provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion

A health effects document for a microorganism shall address, as specified in a work assignment: (1) physical and biological properties of the microorganism; (2) occurrence and environmental fate and transport; (3) infectivity; (4) human exposure to the microorganism; (5) health effects for animals; (6) health effects for humans; (7) mechanisms of infectivity; (8) magnitude of infectious disease effects; (9) a summary of the results of health effects documents prepared by other Federal agencies; and (10) any other areas set forth in the work assignment.

During the development of a health effects document, the contractor shall conduct literature reviews to augment the file of references provided by the EPA PO/WAM with other references.

3.1.5 The contractor shall prepare, evaluate, and revise health advisories for microorganisms. A health advisory provides information that public health officials use to help determine control priorities for pollutants in water as well as providing general information for the public. The contractor shall document the methodology, assumptions, and rationale used to prepare, evaluate, and revise a health advisory. EPA will make the final decision concerning any recommended health advisory based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

A health advisory for a microorganism shall address: (1) general information and properties of the microorganism; (2) occurrence and environmental fate and transport; (3) infectivity; (4) health effects in animals and humans; (5) treatability; (6) magnitude of infectious disease effects; and (7) any other areas set forth in the work assignment.

During the development of a health advisory, the contractor shall conduct literature reviews to augment the file of references provided by the EPA PO/WAM with other references.

3.1.6 The contractor shall provide technical support for the preparation, evaluation, and revision of hazard, exposure, or risk assessment/characterization techniques or methodologies for human health protection. This includes, among other things, providing technical support during the development of methodologies used to develop human health criteria for various water media. The contractor shall document the methodology, assumptions, and rationale used for this task.

EPA will make the final decision concerning any recommended technique or methodology based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.7 The contractor shall provide on a rapid response basis (as defined in 2.6) analyses of human health risk assessment guidelines for microorganisms, results of human health risk assessments, and treatment technology practices and procedures. This includes, among other things, analysis of the impact of criteria on sensitive populations, and analyses of dose response and infectivity data and exposure data.

3.1.8 The contractor shall prepare, evaluate, and revise technical guidance documents and position papers for microorganisms. These documents provide information on the principles for criteria development (e.g., minimum data requirements and exposure assumptions). The contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning any recommended technical guidance document based on

its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.9 The contractor shall evaluate "raw" data generated from an infectivity or epidemiology study. The raw data will be provided by the EPA PO/WAM. The evaluation shall include a complete description of the protocol used to gather the data; analyses of effects observed, including tabulation of all observations; evaluation of biological significance of endpoints according to EPA published guidelines or other technical documents; statistical analyses of the significance of observations; and conclusions as to existence of exposure-related effects and their implications for human health.

3.1.10 The contractor shall conduct appropriate statistical analyses of infectivity data, or epidemiological data, or exposure data, as specified in a work assignment. These analyses shall be completed in accordance with EPA published guidance or other technical documents.

3.1.11 The contractor shall provide analyses of food and water consumption patterns and associated exposure to infectious agents through foods for the U.S. population. These analyses shall include frequency and amount of specific foods consumed by sex, age, and geographical locations. Data to be analyzed shall include data from Federal data collection efforts, State collection efforts, and special studies. Similarly, the contractor shall provide analyses of exposure data from the Center for Disease Control National Health and Nutrition Examination Survey data base and the EPA National Human Exposure Assessment Survey data base, water quality data from U.S. Geological Survey and morbidity and mortality data on food and waterborne illnesses from available databases and other sources as deemed appropriate.

3.1.12 All of the above tasks and deliverables shall be completed in accordance with EPA published guidelines where available.

3.2 Sewage Sludge

3.2.1 The contractor shall provide technical support during the preparation, evaluation, and revision of procedures for selecting microbial pollutants-of-concern in sewage sludge that is used or disposed of, and shall provide technical support during the evaluation of those pollutants. The contractor shall document the methodology, assumptions, and rationale used for conducting this task. EPA will make the final decision concerning any recommended procedures to be used to select pollutants-of-concern and the evaluation of those pollutants based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.2.2 The contractor shall conduct exposure pathway risk assessments for microbial pollutants in sewage sludge applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator. The pathways evaluated for each use or disposal practice shall be the pathways evaluated for each use or disposal practice when the Standards for the Use or Disposal of Sewage Sludge (40 CFR Part 503) were developed, as well as other pathways specified in a work assignment. Results of these risk assessments will be used by EPA to develop limits for pollutants in sewage sludge.

3.2.3 The contractor shall provide technical support during the development of the rationales for the technology-based requirements in a sewage sludge use or disposal standard for pathogens and vector attraction reduction. The contractor shall document the methodology, assumptions, and rationales for this task (e.g.,

the rationale for the 38 percent volatile solids reduction requirement for vector attraction reduction). EPA will make the final decision concerning any recommended operational standard for pathogens and vector attraction reduction based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.2.4 The contractor shall prepare, evaluate, and revise technical support documents for a standard for the use or disposal of sewage sludge. These documents contain the rationales for the requirements (i.e., general requirements; pollutant limits; management practices; operational standards; and frequency of monitoring, record keeping, and reporting requirements) in a sewage sludge use or disposal standard (see 40 CFR Part 503). The contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning any recommended technical support document based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

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3.3.1 The contractor shall have statistical analyses capabilities to perform analyses of environmental data for microbial pollutants to derive descriptive or interpretative statistics.

3.3.2 The contractor shall conduct laboratory/field studies to support the development of water quality criteria, sewage sludge pollutant limits, and other program requirements, as specified in a work assignment.

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3.5 Rule making support

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3.6 Preparation of outreach materials

3.6.1 The contractor shall develop outreach materials in support of the tasks in this PWS. These materials include brochures, presentation boards, slide shows, fact sheets, pamphlets, posters, videos, INTERNET layouts, and models. The materials shall be developed for use in media events (e.g., press releases). In addition, the contractor shall provide materials for distribution at presentations. All materials shall be provided in accordance with the limitations set for in the Section H clause titled "PRINTING (EPAAR 1552.208-70)." The contractor shall provide a draft of all materials for approval by the EPA PO/WAM, and shall prepare the final materials based on the EPA PO's/WAM's comments on the draft materials. For print products, the contractor shall provide a camera-ready copy or digital equivalent, and a disk copy in a disk format that enables the material to be loaded onto the INTERNET. This task shall be done only in direct support of the technical requirements in this PWS.

3.6.2 The contractor shall provide, when included in a work assignment, a complete and accurate translation of foreign language articles cited in a criteria document, a health advisory, or a technical guidance document. Translations shall be performed by experienced scientific translators well-versed in statistical, biomedical, microbiological, or epidemiological terminology. The contractor shall insure that there are no terminology or language usage ambiguities that make interpretation and analysis of the findings difficult. No translations shall be made without the written approval of the Project Officer.

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EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment		Work Assignment Number B-08								
		<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:								
Contract Number EP-C-11-005		Contract Period 01/01/2011 To 12/31/2011 Title of Work Assignment/SF Site Name AWQC for Pathogens								
Contractor ICF INCORPORATED, L.L.C.		Specify Section and paragraph of Contract SOW 3.1, 3.3, 3.4, 3.6								
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Work Plan Approval		<input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Incremental Funding Period of Performance From 07/25/2011 To 12/31/2011								
Comments:										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:				LOE: 0				
01/01/2011 To 12/31/2011										
This Action:						785				
						/785				
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:		Cost/Fee:				LOE:				
Cumulative Approved:		Cost/Fee:				LOE:				
Work Assignment Manager Name Sharon Nappier						Branch/Mail Code:				
						Phone Number 202-566-0740				
(Signature) _____ (Date) _____						FAX Number:				
Project Officer Name Shirley Harrison						Branch/Mail Code:				
						Phone Number: 202-566-1107				
(Signature) _____ (Date) _____						FAX Number:				
Other Agency Official Name Shirley Harrison						Branch/Mail Code:				
						Phone Number: 202-566-1107				
(Signature) _____ (Date) _____						FAX Number:				
Contracting Official Name Donna Reinhart						Branch/Mail Code:				
						Phone Number: 513-487-2114				
(Signature) _____ (Date) _____						FAX Number:				

**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT #B-08**

Title: Activities to support the development of Ambient Water Quality Criteria for Pathogens

Work Assignment Manager: Sharon Nappier (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Phone (202) 566-0740
E-mail: nappier.sharon@epa.gov

Alternate WAM: John Ravenscroft (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

Period of Performance: Work Assignment Issuance through December 31, 2011

LOE: 785 hours

Contractor SOW: 3.1, 3.3, 3.4, 3.6

****Note:** No CBI data will be needed in the course of this work assignment.

Background:

Human health ambient water quality criteria (AWQC) are numeric values limiting the amount of chemical or microbial agents present in our nation's waters. Human health criteria are developed under Section 304(a) of the Clean Water Act of 1972 and are designed to protect human health. Water quality criteria are developed by assessing the relationship between pollutants and their effect on human health and the environment. These criteria are used by states and Indian tribes to establish water quality standards and ultimately provide a basis for controlling discharges or releases of pollutants.

EPA has published AWQC for bacteria. Historically EPA has based the bacteria criteria on fecal indicator bacteria (FIB). These organisms do not cause human illness themselves (that is, they are not human pathogens); rather, they are merely indicators of fecal contamination and therefore indicators of the potential presence of human pathogenic organisms.

The EPA is now interested in creating AQWC for Pathogens. EPA believes that these Pathogen Criteria must be scientifically sound, implementable for broad CWA purposes, and provide for improved public health protection.

Quality Assurance:

The tasks 2-4 in this work assignment require the use of secondary data and require a QAPP specific to the activities being conducted. Consistent with the Agency's quality assurance (QA) requirements, the Contractor must supplement the quality assurance project plan (QAPP), required under Task 1 of this work assignment, to assure the quality of the secondary data or any other types of data used under this work assignment. The QAPP must be approved by the EPA WAM before activities using secondary data begin.

The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1 and should follow the attachment titled, QAPP Requirements for projects using secondary data.

Statement of Work: The scope of work in this assignment will fall under the following task areas. Any technical direction under this work assignment, the EPA WAM will provide to the PO and CO within 5 days.

TASK 1 – Workplan and Monthly Progress Reports

The Contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the Contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the Contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The Contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs' broken out by the tasks in this WA.

Task Area 1.1. Develop project specific QAPP

The tasks 2-4 in this work assignment require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must create a project specific quality assurance project plan (QAPP) to assure the quality of the

secondary data and other data collected to be used under this work assignment. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports and should follow Attachment 1 titled, QAPP Requirements for projects using secondary data.

The work plan shall explain when the QAPP will be submitted based on the specific data requirements of the WA. All projects in Tasks 2-4 that involve secondary data must have an approved QAPP prior to the commencement of work.

Task 2 - Re-evaluate, Update, and Finalize the *Methodology for Deriving Microbial Ambient Water Quality Criteria (AWQC) for Recreational Designated Uses for the Protection of Human Health*

In 2006, EPA drafted the recommended *Methodology for Deriving Microbial AWQC for Recreational Designated Uses for the Protection of Human Health*. The Microbial Methodology is guidance for scientific human health assessments used by EPA to develop, publish, and revise, recommended criteria for water quality accurately reflecting the latest scientific knowledge. The recommended criteria would serve states' and tribes' needs in their development of water quality standards under §303(c) of the CWA.

The Contractor shall finalize the *Methodology for Deriving Microbial AWQC for Recreational Designated Uses for the Protection of Human Health* for publication. The most recent document underwent External Peer Review in 2006. However, the Contractor shall update and re-evaluate the document to reflect the most recent draft *Microbiological Risk Assessment (MRA) Tools, Methods, and Approaches for Water Media* and the current scientific literature. Process steps for re-evaluating, updating, and finalizing the document will be provided through Technical Direction.

TASK 3 – Ambient Water Quality Criteria for Pathogens

Task Area 3.1 Scope of the Criteria Documents

This task will require the Contractor to assist scoping the AWQC for Pathogens for recreational designated uses. Pathogens of immediate interest include, but are not limited to, viruses and protozoa. EPA is considering one criterion document for viruses, such as enteroviruses and noroviruses, and another for protozoan pathogens, such as cryptosporidium and giardia. The Contractor shall assist in drafting an outline of pathogen criteria for viral and protozoan pathogens and identifying the needs of the criterion documents.

Task Area 3.2 *Derivation of the Criteria Values*

Drawing on the draft *Microbiological Risk Assessment (MRA) Tools, Methods, and Approaches for Water Media* and the *Methodology for Deriving Microbial AWQC for Recreational Designated Uses for the Protection of Human Health*, the Contractor shall develop AWQC values for the pathogens of interest. Specific pathogens and the order of importance will be provided through Technical Direction.

Task Area 3.3 *Develop Criterion Document Drafts*

The Contractor shall provide draft documents of the AWQC for Pathogens. Again, specific pathogens and the order of importance will be provided through Technical Direction. This task will be an ongoing effort for the period of performance of this work assignment and a series of Drafts are expected.

Task Area 3.4 *Prepare and submit Final AWQC Criterion for Pathogens*

The Contractor shall prepare and submit a Final AWQC document. In accordance with the contract this document shall be 508 Compliant. The EPA WAM will provide technical direction for the format of the document.

Task Area 3.5. *Prepare briefing materials and other supporting documents pertaining to the Pathogen Criteria documents*

Briefing materials and other supporting documents will be needed during the Criteria development process. The Contractor shall aid in the development of any materials or presentations for these purposes.

Travel: No contractor travel outside of the Washington, D.C. metro area is anticipated for this task.

Task Area 4 - General Project Support

The Contractor shall, based on technical direction given by the EPA WAM, provide support in preparing interim project update and other materials for internal and external audiences. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The Contractors may be requested to participate in and/or conduct briefings. A weekly update call with the EPA WAM will be required for this work assignment, as needed.

Travel: No Contractor travel outside of the Washington, D.C. metro area is required.

Task No.	DELIVERABLE	Schedule
1	Work Plan	Within 15 calendar days of receipt of WA
	1.1 Project Specific QAPP	Within 15 calendar days of receipt of WA
2	2.0 Re-evaluate, update, and finalize the <i>Methodology for Deriving Microbial Ambient Water Quality Criteria for Recreational Designated Uses for the Protection of Human Health</i>	TBD
3	3.1 Scope of the Criteria documents	TBD
3	3.2 Derivation of the Criteria Values	TBD
	3.3 Develop Criteria Document Drafts	TBD
3	3.4 Submit Final AWQC Criterion for Pathogens	TBD
3	3.5 Prepare briefing materials and other supporting documents	TBD
4	4.0 General Project Support	TBD

Travel: Any travel directly related to this work assignment must be approved in advance by the EPA WAM and PO.

Knowledge and Skills Required: The Contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The Contractor shall have practical experience in conducting microbial risk assessments and have advanced credentials in environmental microbiology and/or environmental engineering. The Contractor shall be familiar with the use of fecal indicator organisms, microbiological analytical methods (including molecular techniques), water monitoring applications of epidemiological data, determination of human exposure to environmental contaminant sources, and gastrointestinal disease endpoints.

General Requirements of the Work Assignment and Schedule:

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

Attachment 1

QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

SECTION 1.0, PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES

- 1.1 The purpose of study shall be clearly stated.
- 1.2 Project objectives shall be clearly stated.
- 1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.
- 1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, ~~statistical~~ data analysis (i.e. statistical analysis & any other types of data analysis), and assumptions/recommendations based on the data analysis, if applicable, shall be included.
- 1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

SECTION 2.0, SOURCES OF SECONDARY DATA

- 2.1 The source(s) of the secondary data must be specified.
- 2.2 The rationale for selecting the source(s) identified shall be discussed.
- 2.3 The sources of the secondary data will be identified in any project deliverable.

SECTION 3.0, QUALITY OF SECONDARY DATA

- 3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if

applicable. (If appropriate, a related QAPP containing this information can be referenced.)

- 3.2 The procedures for determining the quality of the secondary data shall be described.
- 3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

SECTION 4.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

- 4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.
- 4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.
- 4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment		Work Assignment Number B-09								
		<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:								
Contract Number EP-C-11-005		Contract Period 01/01/2011 To 12/31/2011 Base <input checked="" type="checkbox"/> Option Period Number								
Contractor ICF INCORPORATED, L.L.C.		Title of Work Assignment/SF Site Name Ratio of cyanotoxins to chl-a								
Specify Section and paragraph of Contract SOW Tasks 2-4										
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 07/15/2011 To 12/31/2011								
Comments:										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund </div>										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO (Max 2) <input type="checkbox"/>										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:				LOE:		0		
01/01/2011 To 12/31/2011										
This Action:								390		
								390		
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:		Cost/Fee:				LOE:				
Cumulative Approved:		Cost/Fee:				LOE:				
Work Assignment Manager Name Lesley Vazquez-Coriano _____ (Signature) (Date)						Branch/Mail Code: Phone Number 202-566-1125 FAX Number:				
Project Officer Name Shirley Harrison _____ (Signature) (Date)						Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:				
Other Agency Official Name _____ (Signature) (Date)						Branch/Mail Code: Phone Number: FAX Number:				
Contracting Official Name Donna Reinhart _____ (Signature) (Date)						Branch/Mail Code: Phone Number: 513-487-2114 FAX Number:				

PERFORMANCE WORK STATEMENT
ICF CONTRACT # EP-C-11-005
WORK ASSIGNMENT # B-09

TITLE: Development of the ratio of Microcystin-LR to Chlorophyll-a and cyanobacteria cell counts in cyanobacterial blooms.

WORK ASSIGNMENT MANAGER: **Lesley Vázquez-Coriano**
U.S. EPA (MC 4304-T)
1200 Pennsylvania Ave. NW
Washington, DC 20460
Phone #: 202-566-1125 Fax #: 202-566-1140
Email: vazquez-coriano.lesley@epa.gov

PERIOD OF PERFORMANCE: Work Assignment Issuance through December 31, 2011

LOE: 390 hours

BACKGROUND

Under certain conditions, cyanobacteria, (also called blue-green algae), could growth creating blooms that could discolor the water, accumulate as readily observable mass populations, and often produce odor compounds. Many types of cyanobacteria have the potential to produce cyanotoxins, and several different cyanotoxins may be produced simultaneously. Among the toxic cyanobacteria, *Microcystis aeruginosa* is commonly observed in highly eutrophic lakes and is one of several cyanobacterial species that can produce microcystin-LR, a heptapeptide toxin responsible of several poisonings of domestic animals and wildlife around the world, and a health hazard for humans through the use of water for drinking and recreation. Many studies have found that microcystin-LR and chlorophyll-a concentrations are highly correlated. Chlorophyll is the green pigment that allows plants to convert sunlight into organic compounds during photosynthesis. Of the several kinds of chlorophyll, chlorophyll-a is the predominant type found in algae. The World Health Organization (WHO) guidelines for safe recreational water environments for coastal and fresh waters adopted a tiered framework which distinguishes three levels of hazards based on cell density and chlorophyll-a concentration as indicators to estimate microcystin-LR concentration in water and predict risks and to determine appropriate responses to microcystin-LR contamination.

In the US, many states have issued guidelines for protection of human health in recreational waters that measures chlorophyll-a concentrations, cyanobacteria cell counts, and/or direct measurements of microcystin-LR. Since EPA does not presently have water quality criteria for microcystin-LR, cyanotoxin, or any other algal toxins, algal densities (chlorophyll-a concentrations and cyanobacteria cell counts) have been used as proxies for the actual presence of algal toxins and to assess the risk of exposure to them.

However, chlorophyll-a concentration is actually an indicator of total phytoplankton biomass and not specifically of cyanobacteria, and high chlorophyll-a concentrations in blooms do not

necessarily result in high microcystin-LR levels. Chlorophyll-a levels, cyanobacteria densities, and cyanotoxin concentrations may change quite rapidly, depending on bloom intensity, species composition and weather conditions so the risk associated with exposure to algal toxins varies by indicator. Currently, how well microcystin-LR occurrence correlates with the occurrence of chlorophyll-a concentrations and cyanobacteria cell counts is unknown. Understanding and establishing a ratio of microcystin-LR to chlorophyll-a could assist states improve current monitoring programs and in establishing protective chlorophyll-a criteria and public health advisory levels for cyanobacterial blooms and cyanotoxins in recreational waters.

STATEMENT OF WORK

The purpose of this effort is to prepare a report to establish a ratio of microcystin-LR levels to chlorophyll-a and cyanobacteria cell counts that will assess the human health risk of exposure to algal toxins in recreational waters. The report should also include a summary of the environmental (e.g. nitrogen and phosphorus ratio and light intensity) and physiological factors that controls and affect the ratio of microcystin-LR to chlorophyll-a, especially the factors related to the growth of toxic cyanobacterial strains in blooms.

QUALITY ASSURANCE

The tasks 2-4 in this work assignment require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor shall prepare a project specific QAPP and ensure the quality of secondary data and other specific data to be used in this WA. In addition, the project specific quality assurance requirements must be addressed in the work plan and monthly progress reports and should follow Attachment 1 titled, QAPP Requirements for projects using secondary data. All projects in Tasks 2-4 that involve secondary data must have an approved QAPP prior to the commencement of work.

TASKS DESCRIPTION

Task 1: Work Plan and Monthly Progress Reports

The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule with deliverables, staffing plan, level of effort (LOE), cost estimate for each task, and the qualifications of proposed staff. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail.

This task also includes monthly progress and financial reports. In each monthly progress report, the contractor shall discuss actual progress toward achieving the purpose of this work assignment, including problems encountered, issues that may need to be resolved, and anticipated timing for completing the goals of the work assignment. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs' broken out by the tasks in the WA.

Task 2: Literature Review and Development of Threshold Values

The contractor shall conduct a literature search of primary and secondary literature on all current information available on:

1. The use of chlorophyll-a concentrations and cyanobacteria density as useful predictors of microcystin-LR toxin concentrations.
2. Other easily measured trophic variables (water clarity, Total Phosphorus, etc) that could be used to correlate with microcystin-LR toxin measurements.
3. Environmental factors (water transparency, water column stability, surface water temperatures, nutrient concentrations, etc) with the greatest influence on the increase of *Microcystis aeruginosa* toxins content in blooms.
 - * Although other cyanobacterial species, such as *Oscillatoria* sp, *Nostoc* sp, *Anabaena* sp, and *Anabaenopsis* sp can also produce microcystin-LR, for the purpose of this report the evaluation of literature and the development of the threshold will be only for *Microcystis aeruginosa* because of its frequent occurrence in toxic blooms worldwide and the related health hazard for humans and livestock.
4. Molecular-based methods and other devices (e.g. fluorometers and spectrofluorimetry with specificity for cyanobacterial pigments) for the detection and analysis of cyanobacterial toxins and pigments particularly for recreational waters.
5. Expected health effects from exposure to different concentrations of microcystin-LR in recreational waters.

The EPA WAM will provide electronic copies of numerous references as a starting point for the literature review.

Subtask 2A:

The contractor shall provide critical review of the literature and develop a draft health risk threshold values that relates microcystin-LR concentration to cell density as well as chlorophyll-a. For each of the threshold values, the contractor shall describe the expected health effects from exposure to microcystin-LR in recreational waters. Provide the draft health risk threshold values to the EPA WAM for review and approval.

Task 3: Draft Report

The contractor shall provide critical review of the literature and prepare a draft report describing the relationship of cell density and chlorophyll-a versus microcystin-LR in terms of:

1. What concentrations of chlorophyll-a, cyanobacteria cell counts or other trophic variables are preindicators of microcystin-LR production.
2. Which conditions of chlorophyll-a levels and cell density may indicate the toxicity levels of *Microcystis aeruginosa* blooms.
3. What are the possible direct and indirect risks of microcystin-LR for human health expected at each health risk threshold?
4. What are the causes of variations in the microcystin-LR ratio?

The draft report should also include:

1. Which environmental factors or conditions have the greatest influence on the increase of microcystin-LR content in blooms?

2. Describe the different approaches and techniques (e.g. fluorescent pigment analysis) to detect cyanobacterial densities and chlorophyll-a determination and provide advantages and disadvantages for each.
3. Suggest effective applications of the health risk threshold values and chlorophyll-measurements for the management of water safety against microcystin-LR exposure based on particular local circumstances.

The contractor shall provide the draft report to the EPA WAM for review and approval.

Task 4: Final Report

The contractor shall prepare final report after the EPA WAM provided comments on the draft report and finalize the health risk threshold values. The contractor shall provide an electronic and paper copy including electronic copies of the references used.

SCHEDULE AND DELIVERABLES:

Task	Description	Timeline
Task 1	Work Plan and Monthly Progress Reports	
	Work plan including the technical approach, resources, timeline, cost estimate, and staffing plan	Within 15 calendar days of receipt of Work Assignment
Task 1a	Project specific QAPP	Within 1 week of WP approval
Task 2	Literature Review and Development of Threshold Values	
	Literature research	One week after work plan approval
Subtask 2A	Critical review of the literature and development of draft health risk threshold values	Two weeks after finalization of Task 2
Task 3	Draft Report	
	Critical review the literature and preparation of draft report	Five weeks after receiving comments from WAM on Subtask 2A
Task 4	Final Report	
	Prepare final report	Two weeks after receiving the final comments from EPAWAM

TRAVEL: No travel required for this work assignment.

General Requirements of the Work Assignment and Schedule:

Knowledge and Skills Required:

The contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The contractor shall have practical experience in conducting toxicological reviews and risk assessments, and have advanced credentials in aquatic ecology, toxicology and/or environmental engineering. The Contractor shall be familiar with freshwater cyanobacteria harmful toxins, phytoplankton physiology and bloom dynamics, analytical methods (including molecular techniques), and determination of human exposure and health effects to cyanotoxins.

Due Dates:

The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date. (see Schedule and Deliverables)

Delays:

The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents:

The Contractor is required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. The EPA WAM will provide comments on draft submissions prior to submission of final documents.

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The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

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A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

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requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

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- 4.3 The expected product document that will be prepared shall be specified (e.g., journal article, final report.).

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number B-09			
						<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001			
Contract Number EP-C-11-005			Contract Period 01/01/2012 To 12/31/2012 Base <input checked="" type="checkbox"/> Option Period Number			Title of Work Assignment/SF Site Name			
Contractor ICF INCORPORATED, L.L.C.				Specify Section and paragraph of Contract SOW					
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 07/15/2011 To 12/31/2011			
Comments:									
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund <div style="text-align: center;">Accounting and Appropriations Data</div> <input checked="" type="checkbox"/> Non-Superfund </div>									
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.									
SFO (Max 2) <input type="checkbox"/>									
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars) (Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1									
2									
3									
4									
5									
Authorized Work Assignment Ceiling									
Contract Period:		Cost/Fee:				LOE:			
01/01/2012 To 12/31/2012									
This Action:									
Total:									
Work Plan / Cost Estimate Approvals									
Contractor WP Dated:				Cost/Fee:		LOE:			
Cumulative Approved:				Cost/Fee:		LOE:			
Work Assignment Manager Name Lesley Vazquez-Coriano <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number 202-566-1125 FAX Number:			
Project Officer Name Shirley Harrison <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:			
Other Agency Official Name <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name Donna Reinhart <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 513-487-2114 FAX Number:			

EPAUnited States Environmental Protection Agency
Washington, DC 20460**Work Assignment**

Work Assignment Number

B-09

☐ Other ☒ Amendment Number:

000002

Contract Number
EP-C-11-005

Contract Period 01/01/2012 To 12/31/2012

Title of Work Assignment/SF Site Name

Base ☒

Option Period Number

Harmful Algal Blooms

Contractor

ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

see PWS

Purpose:

☐

Work Assignment

☐

Work Assignment Close-Out

☒

Work Assignment Amendment

☐

Incremental Funding

☐

Work Plan Approval

Period of Performance

From 01/01/2011 To 12/31/2011

Comments:

WORK ASSIGNMENT B-09 FUNDING CEILING HAVE CHANGED. THE WORK ASSIGNMENT IS FULLY FUNDED.

☐

Superfund

Accounting and Appropriations Data

☒

Non-Superfund

SFO
(Max 2)☐

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:

Cost/Fee:

LOE:

01/01/2012 To 12/31/2012

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated:

Cost/Fee:

LOE:

Cumulative Approved:

Cost/Fee:

LOE:

Work Assignment Manager Name Lesley Vazquez-Coriano

Branch/Mail Code:

Phone Number 202-566-1125

FAX Number:

(Signature)

(Date)

Project Officer Name Shirley Harrison

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

(Signature)

(Date)

Other Agency Official Name

Branch/Mail Code:

Phone Number:

FAX Number:

(Signature)

(Date)

Contracting Official Name Sandra Stargardt-Licis

Branch/Mail Code:

Phone Number: 513-487-2006

FAX Number:

(Signature)

(Date)